S/N 10/600,118

PATENT

CONF. NO. 9143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William W. Cimino	Examiner:	Laura A. Bouchelle
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19US01
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

DECLARATION UNDER 37 C.F.R. § 1.132
BY DR. MARK L. JEWELL, M.D.

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Mark L. Jewell, declare:

1. I am a plastic surgeon certified by the American Board of Plastic Surgery.

2. I possess a Bachelor of Science in Zoology and a Doctor of Medicine from the University of Kansas, Lawrence, Kansas.

3. I have been in private practice performing aesthetic plastic surgery for over 30 years with offices in Eugene, Oregon. In addition to other types of plastic surgery procedures, my practice includes performing lipoplasty, and in particular Ultrasound Assisted Lipoplasty (UAL) procedures, and breast augmentation procedures.

4. I have served in leadership roles for a number of professional societies including as a Governor of the National Endowment for Plastic Surgery (2003-2009); on the Board of Directors for the Plastic Surgery Educational Foundation (2002-2003); on the Board of Directors

of the American Society for Aesthetic Plastic Surgery (2003-2005) and as President from 2005-2006. I am currently the United States National Secretary for the International Society for Aesthetic Plastic Surgery. I have attached a copy of my Curriculum Vitae to this Declaration as Exhibit A.

5. I have published over 60 peer-reviewed scientific papers, books, and book chapters regarding various subjects in the field of cosmetic surgery including lipoplasty procedures. As one example, I authored chapter 55 in the book Innovations in Plastic and Aesthetic Surgery, edited by Marita Eisenmann-Klein, Constance Neuhann-Lorenz, January 2007, which discussed innovations in lipoplasty. I have attached a copy of this chapter to this Declaration as Exhibit B.

6. I have won numerous academic and professional awards including the Tiffany Award in 2003, presented by the ASAPS for best scientific presentation. The presentation was based on work I did in the field of UAL procedures that was published in the Aesthetic Surgery Journal in March/April 2002. The article (Jewell, M.L., Fodor, P.B., DeSouza Pinto, E.D., Al Shammari, M. A., Clinical Application of VASER-Assisted Lipoplasty: A Pilot Clinical Study, Aesthetic Surgery Journal, March/July 2002 22:2, p 131-146) is attached to this Declaration as Exhibit C.

7. I am aware of U.S. Patent Application Serial No. 10/600,118 (the present application) identified above, which is assigned to Sound Surgical Technologies LLC ("Sound Surgical"), and is entitled "Precision Fluid Delivery System and Method for Surgical Procedures." I am aware that the present application is currently rejected by the United States and Trademark Patent Office, and that this Declaration is being submitted in support of arguments against the obviousness of the invention claimed in the present application.

8. It is my understanding that the invention claimed in the present application is embodied in a precision fluid management system (PFMS) sold as part of Sound Surgical's VASER system since 2004.

9. I have used Sound Surgical's VASER system for aesthetic surgery procedures since the VASER system was initially released (without the PFMS), and the updated versions of the VASER system that have incorporated the PFMS.

10. UAL procedures are medical procedures in which fat is removed from areas of the human body. UAL procedures are multistep procedures that first involve a step of infiltrating the fat with a "wetting solution" that may contain epinephrine and local anesthetics. After infiltration, ultrasonic energy is applied to the fat to fragment and emulsify the fat. The ultrasonically treated fat is then removed with suction using a cannula, in an aspiration step.

11. It is common in some breast augmentation procedures to use "sizers" to determine the best size of breast implant to use on a patient. An empty breast sizer is placed inside of a patient and filled with fluid. During the filling, the surgeon can examine the patient and determine when the patient's appearance is ideal. The amount of fluid inserted into a patient is then used to determine the size of the permanent breast implant to use on the patient.

12. Prior to the release of the VASER system incorporating the PFMS, I was not aware of any device that could deliver fluid rapidly and precisely for use in aesthetic procedures such as UAL procedures or breast augmentation procedures.

13. There were two common ways for delivering fluid in aesthetic medical procedures. A first technique involved use of a pressure collar into which a bag of wetting solution was placed. The collar was pressurized to squeeze fluid out of the bag. An example of such a system is the BP-CUFF™ Pressure Infiltrator. Product literature for the BP-CUFF™ Pressure Infiltrator is attached to this Declaration as Exhibit D. A second technique involved the use of syringes with predefined amounts of wetting solution.

14. When using the pressurized cuff device, the amount of fluid delivered was not always precisely known. In UAL procedures, typically, a surgeon would use a tactile and visual approach, i.e. feel the stiffness on the outside of a patient, to determine when to stop the

infiltration. While the use of a syringe provided some precision in the amount of fluid being delivered, the fluid flow rate was unacceptably slow.

15. It is my understanding that the two techniques were the conventional approaches used by surgeons until the release of Sound Surgical's VASER system with the PFMS.

16. It is important in UAL procedures to monitor and control the amount of wetting solution infiltrated into a patient. The amount of fluid used during infiltration is an important factor to ensure effective application of ultrasonic energy to tissue. For example, a typical guideline may be application of ultrasonic energy for 1 minute per 100 ml of infiltration wetting solution. *See Exhibit A, p. 132 ("*. . . . with experience and depending on the anatomic site, it was determined that effective fat fragmentation could be accomplished by using the guideline of a maximum of 1 minute of treatment time per 100 mL of infused wetting solution with the VASER or the continuous mode.*")*.

17. There are also safety implications to being able to precisely monitor and control the amount of wetting solution infiltrated into a patient. As I have noted in literature, "overzealous use of wetting solutions can result in systemic fluid overload, and excessive amounts of local anesthetics intended as regional anesthesia may have deleterious systemic effects." *See Exhibit A, p. 132.*

18. During breast augmentation, it is also important to precisely measure the amount of fluid used in filling breast sizers. As noted above, breast sizers are used by surgeons to determine the size of the permanent breast implants that will provide the ideal aesthetic appearance for a patient. A surgeon must therefore be able to precisely measure the amount of fluid that has been delivered to the sizer in order to be able to select the appropriate permanent breast implant. Inaccurate measurements of the volume of fluid could potentially result in selecting the wrong size implant for a patient.

19. For both breast augmentation and UAL procedures, it is important to deliver fluid rapidly. The rapid delivery of fluid reduces the amount of time a procedure takes which is

important in reducing the likelihood of patient side effects such as infection. For example, when filling breast sizers in a breast augmentation procedure, it is desirable to reduce the amount of time it takes a surgeon to determine the appropriate size of the permanent breast implant, having fluid delivered rapidly to the breast sizer aides the surgeon in making the size determination quickly. Also, rapid delivery of fluid reduces the duration of the procedure and the likelihood of surgeon fatigue during the procedure.

20. Notwithstanding the desirability of delivering fluids both rapidly and precisely for application in aesthetic surgery, no device or method existed in lipoplasty or breast augmentation methods for a number of decades.

21. Sound Surgical's VASER system with the PFMS provided a device that for the first time enabled aesthetic surgeons to deliver fluids both quickly and accurately in aesthetic medical procedures such as. Such a result could not be achieved with prior art devices and methods notwithstanding a need in the industry for such a capability for many years. Sound Surgical's VASER system with the PFMS allows rapid delivery in combination of precise monitoring and control over the amount of wetting solution used to infiltrate a patient's tissue during an UAL procedure or during filling of a breast sizer in a breast augmentation procedure. Sound Surgical's VASER system with the PFMS was the first system I am aware of that was available to the market that precisely monitored rapid fluid flow for aesthetic medical procedures.

22. As I noted in literature:

> The Sound Surgical VASER device can measure volume of wetting solution infused to the cc in a given area. This overcame the imprecise manner that was formerly used of a pressure bag of wetting solution and to look for "tissue firmness" clinically. It was safe to infuse wetting solution approximately a range of 1.5–2 times the anticipated tissue aspirate from a given area.

See Exhibit B, §55.11, Wetting Solution Measurements, p. 446.

23. The ability of the Sound Surgical's VASER system with the PFMS to deliver fluid rapidly and precisely met a long felt need in the industry that improved patient surgical results and reduced possible patient complications such as from fluid overload, introduction of excessive amounts of local anesthetic, and prolonged procedures.

24. Other competitive infiltration systems that I am aware of, e.g., Ez-Pump™ by Mentor and Tumescent Measuring Device by M.D. Resources incorporate the same technology as Sound Surgical's VASER system with the PFMS. It is my understanding that these competitive devices were only offered to the public after Sound Surgical's VASER system with the PFMS was introduced. Other than Sound Surgical's VASER system with the PFMS, and the competitive products mentioned above, I am unaware of any other system or method for rapidly and precisely delivering fluid in aesthetic medical procedures.

25. I am not employed by, or a paid consultant to, Sound Surgical. However, in October of 2004, I was granted options from Sound Surgical to purchase 4,600 membership units (i.e., shares) in Sound Surgical at $4.35 per unit valid through October 2014. I have not exercised any of these options to date. The facts that I describe in this Declaration would be the same regardless of the existence of those options.

26. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

February 17, 2011

Mark L. Jewell

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BY DR. MARK L. JEWELL, M.D.

EXHIBIT A

CURRICULUM VITAE OF DR. MARK L. JEWELL

Mark Laurence Jewell, M.D.

Curriculum Vitae

Professional Offices:

Mark L. Jewell, M.D.P.C.
10 Coburg Road, Suite 300
Eugene, Oregon 97401
541.683.3234
541.683.8610 (fax)
541.913.0067 (cellular)

Electronic mail address:

Dr. Mark Jewell (personal): mjewell@teleport.com
Becky Codington, Dr. Jewell's Administrative Assistant beckyc@markjewellmd.com
Office Communications: mljmd@teleport.com

Website :
www.markjewellmd.com

April 2010

Pre-Doctoral Educational Training:

Pembroke Country Day School; Kansas City, Missouri
Grades 7-12
Class of 1965

Trinity University; San Antonio, Texas; 1965-1967

The University of Kansas; Lawrence, Kansas; 1967-1969
Class of 1969-B.S. Zoology Degree

Doctoral Educational Training:

The University of Kansas School of Medicine; Kansas City, Kansas; 1969-1973
Class of 1973- Doctor of Medicine

Doctoral Education Research Appointments:

Special Museum Assistant, Kansas University 1969
Toxoplasma Research Middle America Research Unit, Panama Canal Zone 1970
Toxoplasma Research Universidad de Antioquia, Medellín, Colombia 1970
Toxoplasma Research Universidad de Costa Rica, San Jose 1971
Toxoplasma Research J.K. Frenkel, M.D. Ph.D. 1970-1972
Executive Committee Midwest Medical Student Research Committee
Membranous Bone Healing Research Department of Plastic Surgery, Kansas University School of Medicine 1973

Doctoral Education Awards:

Russell Hayden Award for Excellence in Student Research 1st Runner up 1971
Participant, Second Annual Midwest Medical Student Research Convention 1971
Sheard-Sanford Award, American Society of Clinical Pathologists 1973
Participant 1973 Student American Medical Association/University of Texas
Medical Branch Student Research Forum
William P. Bailey Award for outstanding research in Pathology 1973
Thomas G. Orr Award for the outstanding Senior Medical Student in Surgery
University of Kansas School of Medicine 1973

Post Graduate Medical Education:

Surgical Internship

Los Angeles County Harbor General Hospital, Torrance California 1973-1974

General Surgery Residency

Los Angeles County Harbor General Hospital, Torrance, California 1974-1976

Burn Fellowship

Los Angeles County University of Southern California Medical Center, 1976-1977

Plastic and Reconstructive Surgery Residency

The University of Tennessee Clinical Education Center
Baroness Erlanger Hospital, Chattanooga, Tennessee; 1977-1979

Microsurgical Training

Duke University Medical Center 1979

Board Certification:

Diplomate, The American Board of Plastic Surgery, November 1981

Medical Licenses:

Kansas
Tennessee
Georgia
California*
Oregon*

*= active

Society Memberships:

American Society for Aesthetic Plastic Surgery
American Society of Plastic Surgeons
American Association of Plastic Surgeons
International Society for Aesthetic Plastic Surgery (ISAPS)
Oregon Medical Association
Oregon Society of Plastic Surgeons
Rocky Mountain Society of Plastic Surgeons
Northwest Society of Plastic Surgeons
Lane County Medical Society
Alpha Tau Omega Fraternity

Private Practice:

Eugene/Springfield, Oregon 1979-current

Professional Society Activities:

The American Society of Plastic Surgery (ASPRS / ASPS / PSEF):

Marketing Committee, ASPRS 1991-1994
Participant, 1991 Marketing Workshop, ASPRS
Chairman, 1992 Marketing Workshop, ASPRS
Chairman, 1993 Marketing Workshop, ASPRS
Chairman, ASPRS Ad Hoc Committee for Informed Consent, 1994-1996
Chairman, ASPRS Publications Committee 1994-1997
Moderator, ASPRS Plastic Surgery On-Line Information System 1994-1997
Faculty Member, ASPRS Spring Institute Symposium 1995
Member Educational Technology Committee, Plastic Surgery Education Foundation National Endowment for Plastic Surgery, network member 1994
Member ASPRS On-Line Committee 1996-1997
Chairman, Patient Consultation Resource Committee 1997-99
Member Outcome and Clinical Guidelines Committee 1999-2000
Plastic and Reconstructive Surgery, Editorial Board-Scientific article reviewer 1998-2008

Leadership Positions:

Governor- National Endowment for Plastic Surgery 2003-2009
Member, Board of Directors, Plastic Surgery Educational Foundation 2002-2003
Member, Board of Directors ASPS 2003-2005
ASPS Board of Trustees 2006-2008
Chairman, Santa Fe Breast and Body Contouring Symposium 2008-2009

The American Board Of Plastic Surgery

Oral Board Examinations- Guest Examiner 2003, 2005, 2007

The American Association of Plastic Surgery

Election to Fellow (Active Member Status) May 2006

The American Society for Dermatologic Surgery (ASDS)

Election to Honorary Associate Member January 2007

International Society for Aesthetic Plastic Surgery (ISAPS)

Communications committee
National Secretary for United Sates of America 2009-2011

The American Society for Aesthetic Plastic Surgery (ASAPS)

Leadership Positions:

Board of Trustees 207-2009
Immediate Past President 2006-2007
Chairman, Board of Trustees, 2006-2007
President, 2005-2006
President-Elect 2004-2005
Vice President Board of Directors 2003-2004
Secretary, Board of Directors 2001-2002
Member at Large, Board of Directors 1999-2001
Parliamentarian, Board of Directors, 1998
Commissioner of Communications 1997-2002
Nominating Committee 1997-1998, 2008, 2009
Executive Committee Board of Directors 2001-2007

Committees and Publications:

Associate Editor Aesthetic Surgery Journal 1993-2005
Vice Chairman, Practice Relations Committee 1994-1997
Chairman, Recent Member Task Force 1994-1997
Instructional Course Faculty 1995-2004
Chairman, Candidate Liaison Program Committee 1995-1998 (founder)
Chairman, Electronic Communications 1996-1998
Chairman, Resident and Fellows Forum Program 1998 (organized by Dr. Jewell)
Breast Implant Task Force 2003-2006 Co-Chair
Breast Implant Work Group Co-Chair (Joint ASAPS-ASPS Work Group)
Injectable Safety Taskforce, Chairman(ASAPS-AAFPRS-AAOPRS-CSAPS-ISAPS-ASPS-ASDS) 2006-Chairman
Cosmetic Medicine Taskforce 2007-2010

Awards:

ASAPS Tiffany Award 2002 for most outstanding scientific presentation during annual meeting-2003
Raymond Klingbel Award for Excellence in Teaching Course Education 2008
ASAPS Traveling Professor Award 2008

Educational Symposia:

Chairman, ASPS-PSEF-ASAPS Santa Fe Brest and Body Contouring Symposium 2008, 2009

Lectureships:

Joyce Kaye Lectureship, American Society for Aesthetic Plastic Surgery, 1998-2004; 2006

Teaching Appointments:

ASAPS Traveling Professor 2006-2008;

Aesthetic Surgery Education and Research Foundation (ASERF)

Treasurer 2007-2008
Vice President 2008-2009

Medical Staff Appointments:

Sacred Heart Hospital, Eugene, Oregon - Active Staff
McKenzie Willamette Hospital, Springfield, Oregon - Active Staff
McKenzie Surgery Center, SCA, Eugene, Oregon-Active Staff

Hospital Staff Activities:

Laser Committee; Surgery Committee; Trauma Committee
Emergency Room Committee; Budget and Technology Committee
Operating Room Committee; Trauma Committee Quality Assurance Sub Committee
Physician Leadership Group- McKenzie Willamette Triad Hospital

Other:

State of Oregon Worker's Compensation Division Carpal Tunnel Guidelines Workgroup 1994-1995
State of Oregon Board of Medical Examiners, Consultant in Plastic Surgery 2000-2009

Academic Affiliations:

Assistant Clinical Professor Plastic Surgery, Oregon Health Science University, Portland, OR

Research Activities

Excaliard Pharmaceuticals 2009-2010
Medicis Corporation- 2007-2009
Medicis-Technologies 2009-2010
Khythera Pharmaceuticals 2009
Allergan (INAMED) Corporation Gel Breast Implant Core Study Investigator 1999-
Allergan(INAMED) Corporation Cohesive Gel Breast Implant Core Study Investigator 2001-
Sound Surgical VASER-pulsed ultrasound lipoplasty Pilot Study Investigator 2000-2001
Mentor Corporation Cohesive Breast Implant Investigator 2002-
Mentor and INAMED Adjunct Study 1994-

Personal Activities/Interests:

5 time Finisher Western States 100-mile run
6 time Finisher McKenzie River 50-mile run
Numerous Marathon races completed >36
CMH Helicopter Skiing Million Foot Award 1990
CMH Helicopter Skiing 2 Million Foot Award 1998
Computer Science ; Cooking
Design / Construction ; Woodworking
White water rafting ; Windsurfing
Bicycling ; Powder Skiing

Computer Science:

Practiceware.com Board of Directors 1999-2002
Microsoft Corporation-Software Beta tester, MS Publisher / Office 1993, 1995, 1996
Spaceworks Corporation-Software Beta tester, version 2.2, 1995

Birth Information:

Kansas City, Missouri USA, October 26,1947

Family:

Married, Wife- Mary Lind Jewell, RPT

Children-	Mark Laurence Jewell II (12-8-76)
	James Lind Jewell (10-17-79)
	Hillary Lind Jewell (5-4-82)

Residence:

4080 Spring Boulevard
Eugene, Oregon 97405 USA
541.484.4750

Publications:

1. Jewell, M.L., et Al, "Development of Toxoplasma Oocysts in Neo-Tropical Felidae", The American Journal of Tropical Medicine and Hygiene, 21:512-517, September 1972.

2. Jewell, M.L., Thompson, D.P., and Frenkel, J.K., "Toxoplasmosis: Titulos de Anticuerpos en Humanos y Gatos de Medellin, Antioquia (Colombia), Antioquia Medica 23:2 145-151 1973.

3. Jewell, M.L. et Al, Comparison of Wound Healing in Wounds Closed with Staples versus Skin Sutures", Contemporary Surgery, 22:1, p 2-32, February 1983.

4. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE , print and electronic media, The American Society of Plastic and reconstructive Surgeons, February 1995.

5. Jewell, M.L. Computer Training, instructional course manual, print and electronic media, The American Society for Aesthetic Plastic Surgery , 1995, 96 pages.

6. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE Supplement , print and electronic media, The American Society of Plastic and Reconstructive Surgeons, November 1995.

7. Jewell, M.L. Lost in the Rush Hour on the Information Superhighway, Editorial, *Plastic & Reconstructive Surgery*: Volume 98(4) Supplement 1 September 1996 pp 721,722

8. Jewell, M.L. ASAPS 1997, CD-ROM format, Instructional disc for computer application training, presentation graphics, and practice development, The American Society for Aesthetic Plastic Surgery 1997

9. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE Supplement , print and electronic media, The American Society of Plastic and Reconstructive Surgeons, October 1997.

10. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE Spanish Edition, print and electronic media, The American Society of Plastic and Reconstructive Surgeons, October 1997.

11. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE Supplement , print and electronic media, The American Society of Plastic and Reconstructive Surgeons, October 1998.

12. Jewell, M.L. Informed Consent and Aesthetic Surgery, Editorial, *Aesthetic Surgery Journal*, Volume 20:2September-July 2000, pp 133-134.

13. Jewell, M.L. PATIENT CONSULTATION RESOURCE GUIDE Supplement , print and electronic media, The American Society of Plastic and Reconstructive Surgeons, October 2000.

14. Jewell, M.L. Commentary on Lipoplasty Safety Article by Charles Hughes, M.D., *Aesthetic Surgery Journal* September/July 2001 21:2, p120-127

15. Jewell, M.L. Prevention of Deep Vein Thrombosis in Aesthetic Surgery Patients, *Aesthetic Surgery Journal* September/July 2001 21:2, p 161-163

Publications:

16. Jewell, M.L. ASAPS 2002, CD-ROM format, Instructional disc for VASER-Assisted Lipoplasty, (The American Society for Aesthetic Plastic Surgery)2002.

17. Jewell, M.L. ASAPS 2002, CD-ROM format, Instructional disc for Advanced Topics Microsoft PowerPoint, (The American Society for Aesthetic Plastic Surgery)2002.

18. Jewell, M.L., Fodor, P.B., DeSouza Pinto, E.D., Al Shammari, M. A., Clinical Application of VASER-Assisted Lipoplasty: A Pilot Clinical Study, *Aesthetic Surgery Journal* March/July 2002 22:2, p 131-146.

19. Casas, L.A., Jewell, M.L., Non-narcotic acute pain relief after ambulatory aesthetic surgery, *Aesthetic Surgery Journal* September/October 2002 • Volume 22 • Number 5, p 493-494.

20. Jewell, ML, Frank W. Masters, M.D. Obituary, *Plastic and Reconstructive Surgery* September 2002 Volume 110(4) p 1181-1182.

21. Jewell, ML, Medical Errors in Aesthetic Plastic Surgery, *Aesthetic Surgery Journal*, March- July 2003, p. 108-109

22. Jewell, ML, David W. Robinson, M.D. Obituary, *Plastic and Reconstructive Surgery*, May 2004 Volume 113(6)p 1863-1864.

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24. Adams,WP, Bengston, BP, Glicksman, CA, Gryskiewicz, Jewell, ML, JM, McGrath, MH, Reisman NR, Teitelbaum, SA, Tebbetts, JB, Tebbetts, T, Decision and Management Algorithms to Address Patient and Food and Drug Administration Concerns Regarding Breast Augmentation and Implants, *Plastic and Reconstructive Surgery*, October 2004 Volume 114(5)p 1252-1257.

25. Rohrich, Rod J. M.D.; Cunningham, Bruce L. M.D.; Jewell, Mark L. M.D.; Spear, Scott L. M.D. , Teenage Breast Augmentation: Validating Outcome Data and Statistics in Plastic Surgery. *Plastic and Reconstructive Surgery*, September 2005 Volume 115(3)p 943-944.

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27. Jewell, M.L., Ted Lockwood, Obituary, *Plastic and Reconstructive Surgery* July 2005 Volume 116(1) p 357-358.

28. Jewell, M.L. Book Review: Aesthetic Medicine Practicing for Success –Marie Czenko Kuechel; *Plastic and Reconstructive Surgery* Reviews; October 2005 Volume 116(5) p 1554-1554.

Publications:

29.Jewell, M.L. Letter to the Editor: RECONSTRUCTION IN WOMEN WITH BILATERAL PROPHYLACTIC MASTECTOMY: A DESCRIPTIVE STUDY *Plastic and Reconstructive Surgery* Reviews; October 2005 Volume 116(5) p 1557-1558.

30. Jewell, M.L., Book Review Medical Malpractice: A Physician's Sourcebook *Plastic and Reconstructive Surgery: Volume* 116(6) November 2005 pp 1805-1806

31. Jewell, M.L. Reduction Mammaplasty Point-Counterpoint- Should Insurance Coverage for Reduction Mammaplasty Be Mandated by Law?, Plastic Surgery News. December 2005, Vol. 16, No. 11, page 6.

32. Jewell, ML Body Contouring in Massive Weight Loss Supplement, *Plastic and Reconstructive Surgery , January 2006, Volume 117, Issue 1*

332. Jewell, ML, Executive Editor, Consensus Recommendations for Soft Tissue Augmentation with Nonanimal Stabilized Hyaluronic Acid (Restylane) (NASHA), *Plastic and Reconstructive Surgery* Vol. 117:3 March 2006, pp. S1-S34.

34. Padsalgikar, Ajay, Jewell, M.L. Young, V L, AorTech Breast Implant Shell Material, in press, *Plastic and Reconstructive Surgery 2006*

35. Ajay Padsalgikar, Jewell, M.L. Young, V L, AorTech Gel Paper, in press, *Plastic and Reconstructive Surgery 2006*

36. Jewell, M .L., Drugs and Devices: Important Considerations, Importing, Re-Importing, and Compounding May Carry Serious Consequences, *BME Report-Oregon Board Of Medical Examiners*, Fall 2005, page 5.

37. Jewell, M.L. *Cycle of Care Workbook Guide for Plastic Surgeons*, Forward Comments, The American Society foe Aesthetic Plastic Surgery, 2006

38. Jewell, M.L. Restylane SubQ in Aesthetic Facial Contouring, *Aesthetic Surgery Journal,* Vol 26:1 January-February 2006, pp. S3.

39. Jewell, ML, Style 410 Implants, Discussion, INAMED Clinical Education Series, July 2006

40. Jewell, ML, Innovation in Plastic and Aesthetic Surgery-Lipoplasty, Book Chapter, January 2007

41. Jewell, M.L. Synmastia After Breast Augmentation, An Avoidable Complication, Discussion, *Plastic and Reconstructive Surgery118:7S,12-2006, 172S-174S.*

42. Adams, WP, Teitelbaum, S, Tebbetts, JB, Jewell, ML, Spear S, Bengtson, B, Breast Augmentation Roundtable, *Plastic and Reconstructive Surgery118:7S,12-2006, 175S-187S.*

43. Jewell, M.L. The MACS Short Scar Facelift- Technical and Strategic Considerations, Book Chapter, Quality Medical Publishing, June 2007

44. Jewell, M.L. Patient Safety, Ultrasonic Lipoabdominoplasty, Advances in Aesthetic Surgery, Chapter 5 and 63, Elsevier 2009

Publications:

45. Jewell, ML, Should OB / GYN's be performing cosmetic plastic/dermatologic procedures? Invited Editorial, *Female Patient*, June 2007.

46. Jewell, ML, VASER Lipoplasty, Book Chapter, Cemal Sunyuva, author 2007

47. Jewell, M.L. Restylane Beyond the Nasolabial Folds, 2007

48. Jewell, ML, Overview of Perlane®, a Volume Enhancing Non-Animal Stabilized Hyaluronic Acid - for Soft Tissue Augmentation 2007

49. Jewell, ML, Staph "Superbug" is a real and dangerous epidemic, Guest Viewpoint, The Register Guard Newspaper, Eugene, Oregon p B3, 11-18-2007.

50. D'Amico, RA. ; Saltz, R; Rohrich, R; Kinney, B; Haeck, P.; Gold, A.; Singer, R.; Jewell, M L. ; Eaves, F, Risks and Opportunities for Plastic Surgeons in a Widening Cosmetic Medicine Market: Future Demand, Consumer Preferences, and Trends in Practitioners' Services.
Plastic & Reconstructive Surgery. 121(5):1787-1792, May 2008.

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52. Jewell, ML, Tissue Fillers, Assessing the Risks, *Aesthetic Surgery Journal*, 28:4 July August 2008, p. 468-469

53. Jewell, ML, ASAPS 2008: Dermal Fillers - Beyond the Basics, Medscape CME, www.medscape.com June 2008

54. Jewell, ML Patient Safety With Injectables Medscape CME, www.medscape.com July 2009

55. Jewell, ML, Safety With Injectables Resource Book, *Physicians Coalition for Injectable Safety*, 2009, electronic publication in Adobe Acrobat .pdf format 112 pages

56. Jewell, ML, Physicians Coalition for Injectable Safety Report, ISAPS News, V5:1, March-June 2009, p 12-13.
57. Jewell ML, Business Plan for Cosmetic Medicine, Book Chapter, Cosmetic Medicine, edited Renato Saltz, MD, Quality Medical Publishing, St. Louis, 2009.

58. Jewell, ML, Jewell JL, A Comparison of Outcomes Involving Highly-Cohesive, Form-Stable Breast Implants From Two Manufacturers In Patients Undergoing Primary Breast Augmentation. Will Quality Programs Reduce the Rate of Surgical Revision? In press, Aesthetic surgery Journal 2009

59. Aston, SJ edit, Aesthetic Plastic Surgery, book chapters on Lipoabdominoplasty and Patient Safety 2010

60. Jewell, M., Commentary on Godron Sasaki paper on Comparative Lipoplasty, Aesthetic Surgery Journal March-April 2010, in press.

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BY DR. MARK L. JEWELL, M.D.

EXHIBIT B

BOOK CHAPTER:

Chapter 55, Innovations in Plastic and Aesthetic Surgery, edited by Marita Eisenmann-Klein, Constance Neuhann-Lorenz, January 2007

Innovation in Plastic and Aesthetic Surgery Lipoplasty

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55.1 Introduction

One of the most remarkable innovations in aesthetic surgery is that of lipoplasty. Mostly, we hear of refinements in surgical technique that merely represent incremental improvements in existing techniques. Lipoplasty, on the other hand, when it was first reported represented a totally new approach for body contouring that had not heretofore been considered. For its inventor, it represented an "a-ha" moment, yet a quarter of a century later, the complete details of this innovation still remain to be discovered [1, 2].

Prior to lipoplasty, the surgical solution for contour improvements was direct excision of areas, with large scars, prolonged recovery time, and unacceptable results for most patients to utilize the existing way that fat deposits were treated before lipoplasty. Disruptions offer better solutions by using approaches never considered formerly to produce better outcomes.

Initially, the announcement of a new form of minimally invasive body contouring surgery produced a lot of excitement for surgeons to learn a new technique. Ultimately, how rapidly lipoplasty was adopted related to providing better, faster, or less-invasive outcomes. While there have been attempts to provide alternative procedures for body contouring with external ultrasound lipoplasty (XUAL), mechanical rollers (Endermologie, LPG Valance, FR), and devices that emit radiofrequency/infrared energy (Thermage, Thermage, Hayward, CA, USA, and Titan, Cutera, Brisbane, CA, USA), surgical lipoplasty remains the procedure of choice for body contouring in most cases. The combination of lipoplasty with excisional body contouring procedures appears to be safe and effective when there is deficient skin tone [3].

55.2 The Evolution of Lipoplasty

It has been an interesting experience to watch both the introduction of lipoplasty technique in the mid 1980s, its adoption by surgeons, and where lipoplasty is today in 2007. The evolution of lipoplasty over the last quarter century has been an interesting mix of incremental improvements regarding technique, wetting solutions, and hardware, and disruptions due to newer lipoplasty technologies [4–6].

Evolutions in the technique of lipoplasty have produced improved outcomes, due to the use of wetting solutions that contain lidocaine and epinephrine. Blood loss has been minimized and recovery enhanced when there is less surgical blood loss and tissue ecchymosis after lipoplasty [7]. Currently, most surgeons are using a variant of the "superwet" technique of infusing between one and one-half to twice the volume of wetting solution to the amount of proposed aspirate. Despite the use of the term "tumescent" technique, very few

surgeons have found benefit with large volumes of wetting solutions.

There have been minor advancements in conventional lipoplasty technology over the large-bore, single port cannulas that Dr. Illouz developed in the late 1970s that were modeled after uterine evacuation cannulas. Cannulas that were designed with sharp cutting edges have proved very damaging to tissue layers. Smaller diameter cannulas with multiple ports were developed that did not inflict as much damage to the collagen tissue matrix. While surgeons were able to perform conventional cannula lipoplasty fairly well, there were still limitations in many areas of the body due to increased collagen content of the tissue matrix and increased resistance to the passage of cannulas through this layer.

55.3 Additional Considerations in Lipoplasty, Beyond Technique

In order for most patients to achieve good to excellent clinical outcomes anywhere in the body it was necessary to consider more than just technology when performing lipoplasty. For this to be accomplished, it was necessary to look beyond plastic surgery and learn from other industries where there exists operational excellence and a process-related approach. In reality, there are similarities to the process of lipoplasty and what occurs in the aviation or automotive industries. Technology certainly has its role, but success in lipoplasty involves a blend of technology, quality improvement, and operational excellence.

55.4 Operational Excellence in Lipoplasty

The concept of how to provide operational excellence and quality improvement in lipoplasty has formerly received minimal thought and action. John Tebbetts, MD, literally dissected the process of breast augmentation, in time and movement studies [8, 9]. In doing this, he found a way to improve the efficiency of the process and improve outcomes. As surgeons, in order to improve quality and safety in lipoplasty our perspective must go beyond the actual performance of the procedure, to encompass a more "holistic" approach that was the entire cycle of care from start to finish.

Plastic surgeons and lipoplasty equipment manufacturers have been focused for years on technical issues rather than how to perform lipoplasty optimally. Conventional approaches to lipoplasty have certain limitations and it is difficult to produce the same quality of outcomes in body areas that have greater collagen content in the tissue matrix layer, i.e., upper abdomen, back and flanks.

55.5 Quality Improvement and Experimentation

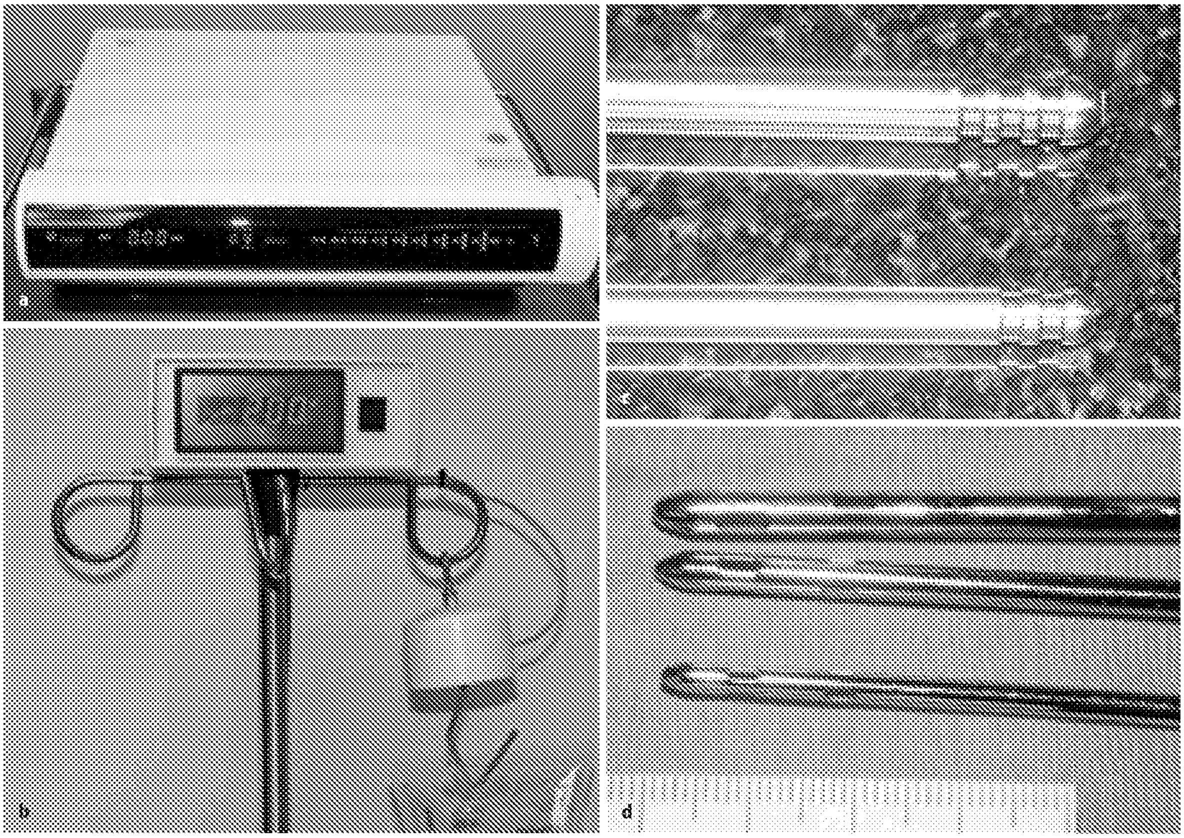
We as surgeons when using conventional lipoplasty confront the same problem, case after case as manifested by inefficiencies, irritations, and occasional catastrophes. We fail to engage in problem solving exercises and experiments in order to solve the problems that we face with lipoplasty. When confronted with a situation where the tissue is very fibrous, we as surgeons tend to think that better results can be produced by more aggressive technique versus rethinking how we can better perform lipoplasty in a difficult area with an energy-based technology (UAL, VAL, or PAL) (ultrasonic assisted lipoplasty, VASER-assisted lipoplasty, power-assisted lipoplasty).

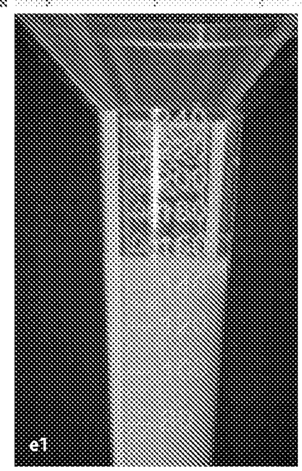
A classic example of living with inefficiencies is the matter of vacuum locking that occurs during cannula lipoplasty when the suction tubing fills with aspirated fat and efficiency in aspiration drops due to a lowering of vacuum pressure at the port of the cannula [10]. This equates to sucking liquid out of a closed space. Air is not allowed to enter in order to release the negative pressure. This is no different than what your office nurse experiences when she attempts to draw liquid out of a closed vial with a hypodermic needle and cannot draw more due to the internal vacuum pressure equaling the suction force of the syringe.

Most of us who perform lipoplasty have noticed this vacuum lock phenomenon, yet have not experienced an "a-ha" moment with regards to solving this problem of inefficient aspiration. The solution to this problem is quite simple, and something that we have used formerly in nasogastric tubes, a small air bleed in the line dramatically increasing flow. While this is a simple solution to the problem of inefficient aspiration, it took years to consider the physics of aspiration for a solution to inefficient lipoplasty aspiration [10].

55.6 The Rise and Fall of Ultrasonic Lipoplasty

UAL (ultrasonic assisted lipoplasty) was initially met with enthusiasm in the late 1990s, but fell into disuse because there was not a process by which this technology could optimally function. Surgeons went about performing UAL within the mindset of conventional lipoplasty because they were trained to do it that way in the UAL Taskforce Courses [11]. It was not that UAL was a poor solution for lipoplasty patients, but we as sur-





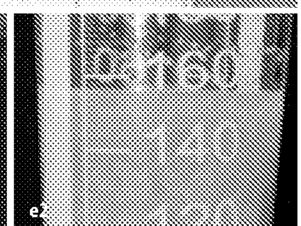


Fig. 55.1. VASER technology. **a** VASER generator. **b** Fluid infuser. **c** Solid titanium probes. **d** VENTX vented cannula. **e** Precision measurement of lipoaspirate

geons blamed the technology when UAL failed to deliver excellent outcomes, instead of realizing that we did not know how to use it optimally and safely. Unfortunately, these devices were based on a cannula lipoplasty model with large-bore UAL cannulas and inefficient 2 mm aspiration lumens [12].

It is not surprising that second generation UAL failed. Second generation UAL in retrospect was a "perfect storm":

- Marketing free-for-all between equipment manufacturers
- Inadequate training courses
- UAL cannulas that removed protective wetting solutions during fragmentation, sharp-edged UAL cannula that cut tissue
- No science whatsoever to determine the optimum power range and length of fragmentation time
- Non-precise measurements of wetting solution infused or fat aspirated

For there to be progress in overcoming the limitations that existed in conventional lipoplasty and second-generation UAL, I felt that it was necessary to look at the entire process, akin to the Toyota Production System, where emphasis is placed on delivering operational excellence and eliminating a work-around culture. This was not a cookbook approach for lipoplasty, but an emphasis on finding ways to improve problems that currently exist.

55.7 More on Quality Improvements in Lipoplasty

If one objectively looks at lipoplasty, it was a crude, imprecise, somewhat brutal form of body contouring that had ill-defined approaches and end points. There was little data that demonstrated safety and quality of out-

comes. There were also unusual clusters of morbidity and mortality when surgeons attempted to use this approach for large volume removal of fat.

The matter of patient morbidity and mortality from a procedure that formerly was considered to be "safe" caused a rethinking of decisions to remove fat volumes greater than 5 liters in a single setting, better monitoring of lidocaine-containing wetting solutions to not exceed 35 mg/kg, and ways to prevent venous thromboembolism during surgery. When these factors were addressed by surgeons, the morbidity and mortality from lipoplasty improved significantly [13–15].

Begging the question, had we really made any progress in a quarter century of lipoplasty when there are:

- Inefficient cannula designs that damage tissue matrix
  - Low-efficiency UAL that primarily deliver heat to tissue as opposed to efficient fragmentation
- Imprecise administration of wetting solutions and aspirate measurement
  - Side-to-side discrepancies in aspirate volume
- Garments with no science whatsoever

Inadequate surgical practices:

- Wrong mindset:
  - "Get it over as quickly as possible"
  - "Large bore 6 mm cannulas work just fine"
  - "I'm satisfied with how I do lipoplasty"
  - "My patients aren't asking for anything fancy"
- Poor aesthetic goals:
  - Spot reduction of fat deposits
  - Failure to treat regional aesthetic units
  - Failure to treat circumferential or three dimensions

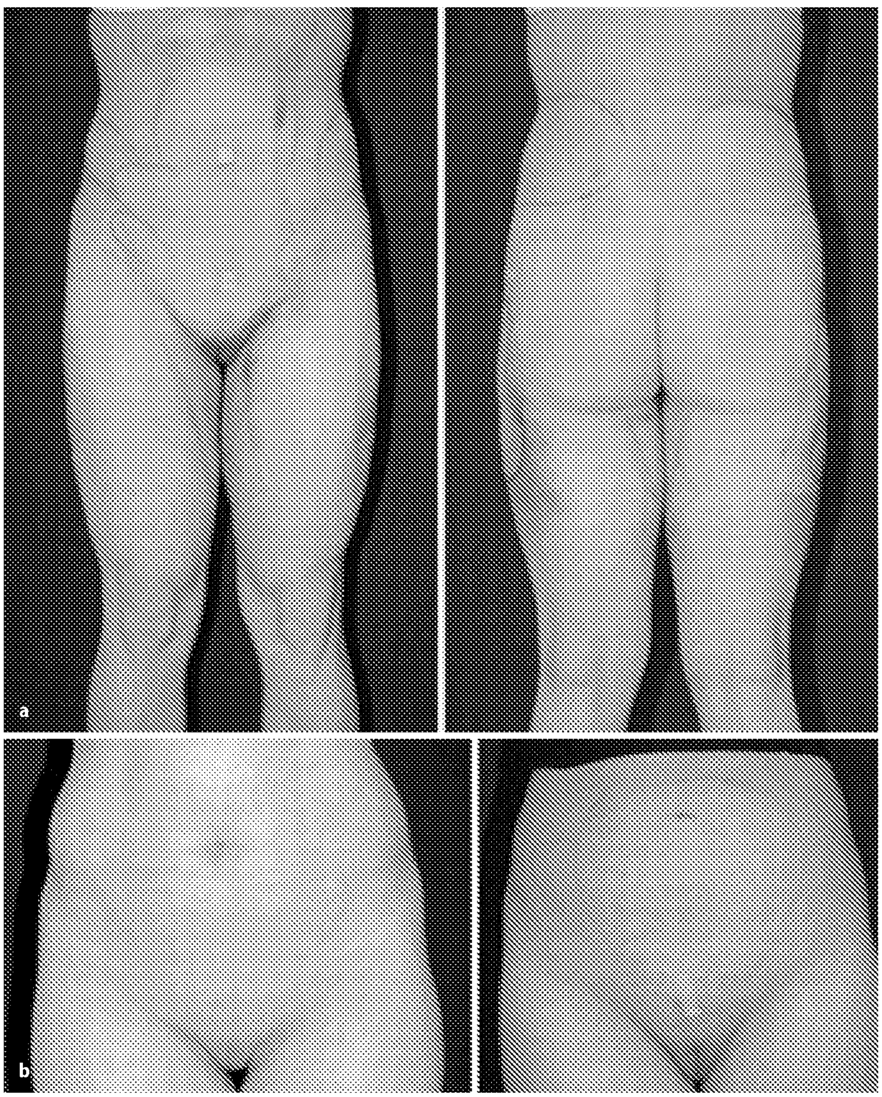


Fig. 55.2. **a** Patient 24 h post 2,400 cc VASER lipoplasty. There is minimal ecchymosis and pain. **b** No ecchymosis 24 h post 800 cc VASER lipoplasty of abdomen

55.8 Third-Generation Lipoplasty Devices

When I received my first VASER UAL System (Sound Surgical Technologies, Louisville, CO, USA) in 2000, a third generation UAL device that used pulsed ultrasonic energy and solid titanium side-grooved probes, I made a decision to see what would happen if greater attention was paid to each component of the process of ultrasonic lipoplasty in order to improve the quality of outcomes and to lessen the rate of complications. Peter Fodor, MD, and Ewaldo Bolivar DeSouza Pinto, MD, also received the initial VASER devices. We conducted the initial Pilot Clinical Study regarding the VASER.

The VASER, while using ultrasonic energy to fragment fat, like earlier UAL devices, optimized the fragmentation of fat through high-efficiency solid probes [16–18].

55.9 UAL Complications

First, I thought that it was important to look at the data regarding why there were complications reported with UAL and to see if there were root causes that could be corrected. When the published reports of complication for second-generation UAL were analyzed from the 14 papers that had been published, the data confirmed [6] (Table 55.1).

Complications were categorized into nine areas to determine the root cause (Table 55.2).

Table 55.1. Complications

Range of complications	0–100%
Mean complication (average)	13.5%
Median complication	4.90%
Overall complication	7.90%

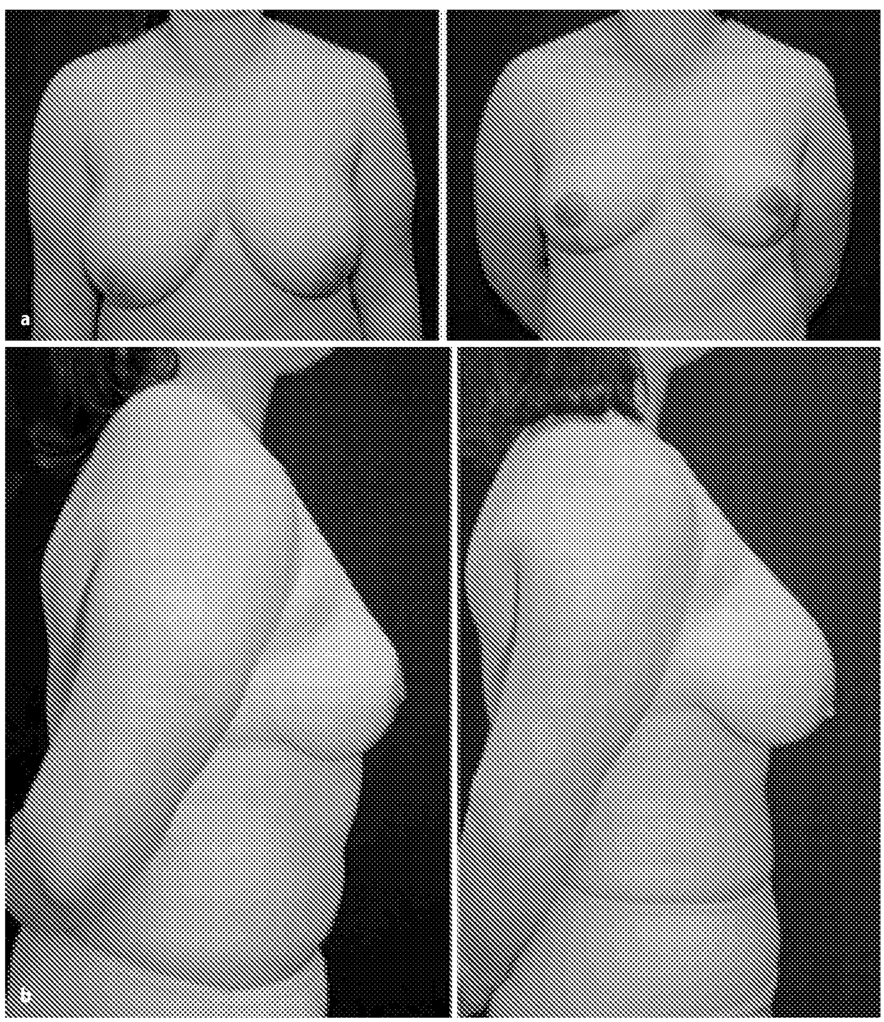


Fig. 55.3. Breast reduction with VASER technique: 850 cc wetting solution/side; 20 min fragmentation time/side; 800 cc lipoaspirate; vertical mastopexy

Table 55.2. Complications categorized into nine areas

Category	Overall incidence	Mean	Median
Sensation change*	2.3%	7.0%	0.2%
Seroma*	2.2%	4.8%	1.25%
Induration*	0.1%	3.6%	0%
Skin necrosis*	1.5%	1.6%	0%
Hyperpigmentation	1.2%	0.5%	0%
Prolonged swelling*	0.3%	0.3%	0%
End hits*	0.1%	0.2%	0%
Burns*	0.1%	0.1%	0%
Cellulitis	0.1%	0%	0%

* ●●●

55.10 A Pathway to Improve Quality and Safety in Ultrasonic Lipoplasty

This data confirmed that causes for UAL complications were not a random occurrence, but related to surgeon determined factors:

- Excessive ultrasonic energy applied to tissue
- Inadequate amounts of wetting solutions
- Excessive tissue trauma during aspiration
- Poor surgical technique – burns and end hits
- Ill-defined endpoint regarding tissue fragmentation
- Ill-defined endpoints regarding aspiration

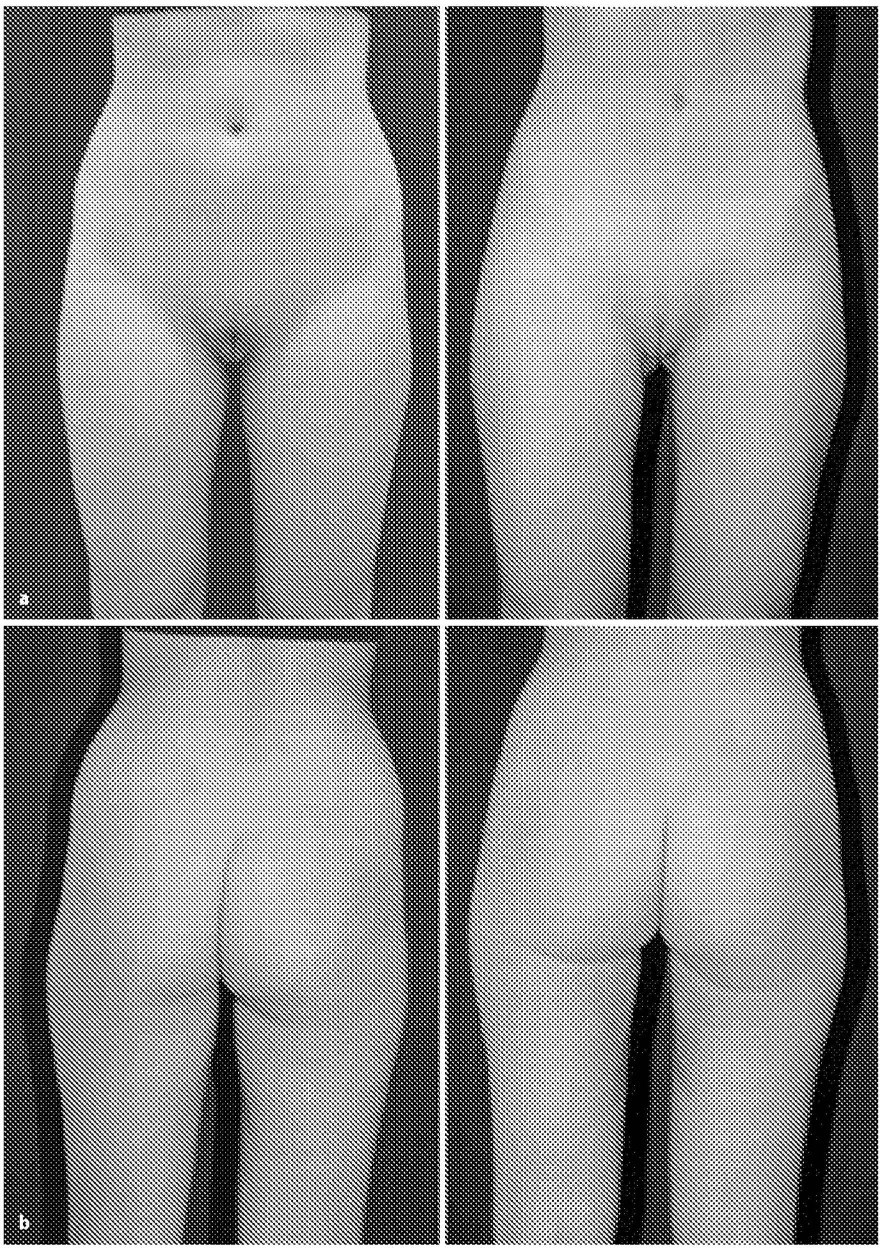


Fig. 55.4. Twelve month follow-up after VASER lipoplasty to upper/lower abdomen, posterior waist, inner and outer thighs 2,600 cc lipoaspirate

Fig. 55.5. Typical VASER lipoaspirate sample, 95 % fat

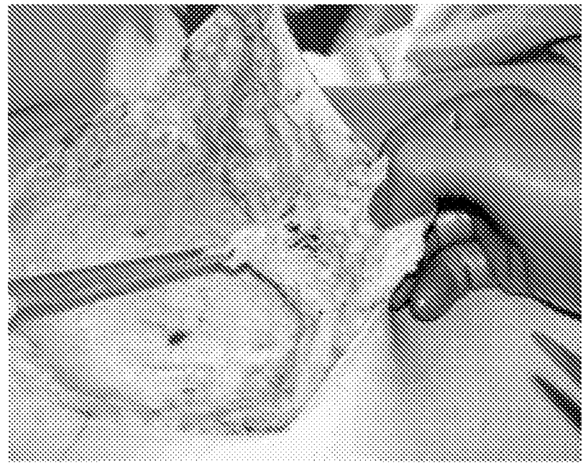


Fig. 55.6. VASER lipoplasty is very effective in the mid-lamellar level, just above Scarpa's fascia. It can be used as a solitary procedure in selected patients, or combined with excisional procedures such as lipoabdominoplasty, body lifts or brachioplasty

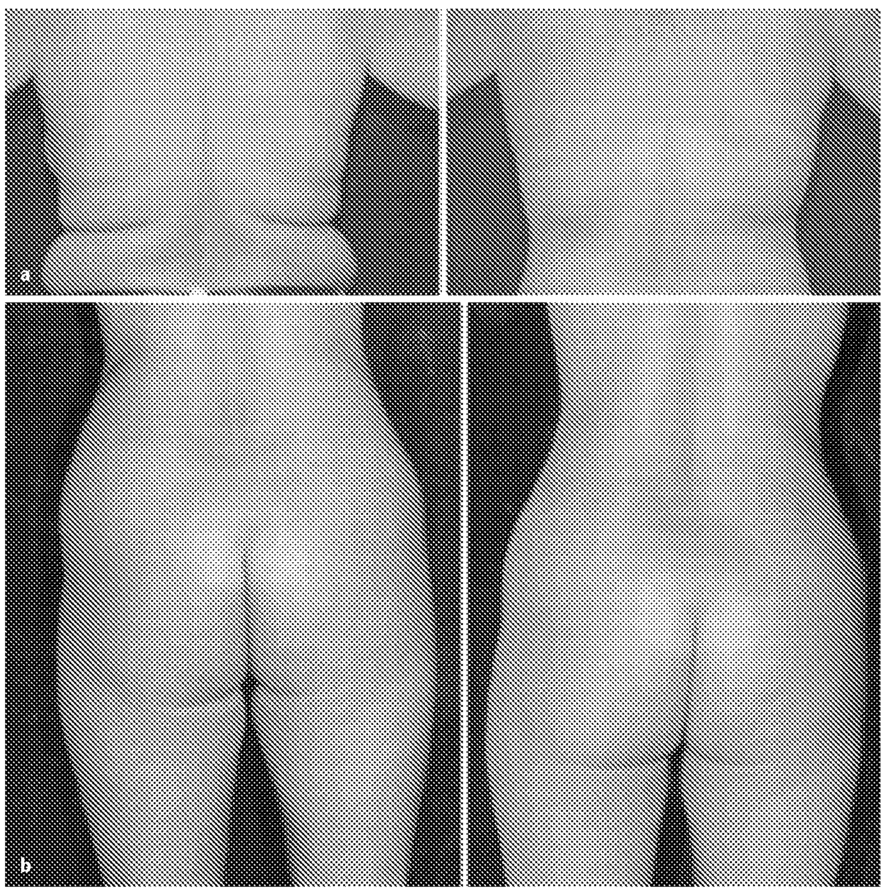


Fig. 55.7. a VASER lipoplasty is effective in fibrous-difficult to treat areas such as back and lumber rolls. b Posterior waist VASER lipoplasty before/after

55.11 The Process of VASER Lipoplasty

The cycle of care in lipoplasty from the start to finish involves patient assessment, management of expectations, a surgical strategy, surgical excellence, and aftercare. Documentation of clinical decisions regarding how surgery would be performed and how patient care is delivered documents the quality of lipoplasty outcomes. Forms and worksheets are necessary for planning and performance of lipoplasty [19].

55.12 Wetting Solution Measurements

My approach was to base the amount of fragmentation time on the amount of wetting solution infused into a given tissue area. By this approach, excessive ultrasonic energy is not applied that would otherwise damage the tissue matrix and produce complications as listed above. The Sound Surgical VASER device can measure volume of wetting solution infused to the cc in a given area. This overcame the imprecise manner that was formerly used of a pressure bag of wetting solution and to look for "tissue firmness" clinically. It was safe to infuse wetting solution approximately a range of 1.5–2 times the anticipated tissue aspirate from a given area.

55.13 Tissue Fragmentation Time

Excessive application of ultrasonic energy to tissues was also considered as part of a quality improvement process versus extremely long ultrasonic energy times as formerly published. The initial approach was to use 1 min of VASER fragmentation time per 100 cc of wetting solutions infiltrated into a given tissue area. When this guideline was followed, there were no complications in the Initial VASER Clinical Pilot Study paper population that were formerly seen in UAL [6]. Since then, VASER times for tissue fragmentation have increased, 1 min in soft tissue, 2 min in firm tissue areas and 2½ min in the female breast per 100 cc of wetting solution infiltrated into a given area.

The Sound Surgical VASER (Vibration amplification of sound energy at resonance, Sound Surgical Technologies, Louisville, CO, USA) represents a third-generation ultrasonic lipoplasty device that uses side-grooved solid titanium probes versus the hollow UAL cannula from the second-generation devices. The smaller probes require about one-fourth of the energy required in older devices to efficiently fragment fatty tissue. The side grooves of the VASER probes help disperse the ultrasonic energy from the tip area to the sides of the probe in order to diminish the risk of burns. Finally, the VASER probes use pulsed ultrasonic energy versus a continuous application of energy. This allows for efficient fragmentation of fat without excessive heating of the tissue.

55.14 Clinical End Points: Fragmentation

In addition to the clinical guideline of time per 100 cc of wetting solution infiltrated, another end point was that of loss of resistance to VASER probe movement. If it became possible to pass the VASER fragmentation probe with two fingers, before the time limits, it was a safe time to stop. For novices, the initial guideline of 1 min per 100 cc of wetting solution infiltrated into a given area is a good starting point.

The key concept here is to avoid too much ultrasonic energy applied to tissues in order to prevent burns, sensory nerve dysesthesias, and collateral damage to the collagen tissue matrix. Second generation UAL devices that simultaneously fragment tissue and aspirate remove the protective effect of wetting solutions designed to prevent excessive thermal damage to tissue.

55.15 Tissue Evacuation

Tissue evacuation was the next factor to analyze when improving the process of lipoplasty. Besides the problem of vacuum lock, existing lipoplasty cannulas were traumatic to the collagen matrix and damaged blood vessels, lymphatics, and nerves. Smaller bore, vented cannula that were more fat-specific and less prone to damaging the collagen matrix were needed to increase efficiency in aspiration.

Large-sized wall suction canisters are a very inaccurate way to measure the lipoaspirate. A more precise canister system was needed to avoid side-to-side discrepancies in the amount of lip aspirate.

I believe that the process of aspiration is dependent on a keen awareness by the surgeon on the quality and quantity of the lipoaspirate along with a feel for contour changes in the fat deposit. The intended goal of aspiration is to remove fat from treated areas and to spare the residual elements of the collagen tissue matrix (including blood vessels, nerves, and lymphatics). The fat should be aspirated without excessive trauma that will leave blood in the tissue that produces postoperative pain and hyperpigmentation from residual hemosiderin.

Gentle aspiration with a small-bore vented cannula (VENTX, Sound Surgical Technologies) yields a pale-colored lip aspirate. Aggressive techniques with large

bore cannulas or power-assisted devices yield a more bloody aspirate. A simple clinical end point for aspiration is to stop when no more fat is coming out of an area or that the color of the aspirate becomes blood-tinged. It is not necessary to engage in squeezing tissue (sausage rolling) while performing aspiration. This may produce contour irregularities.

55.16 Aftercare, Including Garments and Foam Dressings

Compressive garments and adjunctive techniques to reduce ecchymosis after lipoplasty were another factor to consider. This component of the process of lipoplasty is the least precise and scientific. There is absolutely no data that demonstrates efficacy of compression garments, optimal design, or compression force. Anecdotally, we know that polyurethane foam sheets that are coated on one side with a sticky silicone-based adhesive dramatically reduce ecchymoses after lipoplasty, but there has not been any research into the mechanism of action. Presumably, this material may act in a similar way as taping after a rhinoplasty prevents bruising in the nasal tissue.

Foam has remained a mainstay in my personal lipoplasty technique. I have for the most part abandoned conventional lipoplasty compressive garments (corsets) and use commercial body shaper garments one or two sizes larger than the patient would wear normally. These inexpensive garments appear to work, yet are more difficult to apply when a patient is under general anesthesia than the garments that have side zippers.

55.17 General Anesthesia Vs. IV Sedation

The need for general anesthesia for lipoplasty also remains to be studied. From a surgeon's perspective, it allows for efficiency in the performance of lipoplasty, yet adds risk to the procedure regarding venous thromboembolism, hypothermia, and PONV (postoperative nausea and vomiting), besides increased cost. Lipoplasty performed with warmed, buffered, local anesthetic-containing wetting solutions [20] under conscious sedation or deeper monitored anesthesia care (MAC) may be safer, but slower.

55.18 Expanded Applications for VASER Lipoplasty

Once the initial pilot clinical study confirmed that the approach for VASER lipoplasty (VAL) was safe, additional applications were considered in areas that formerly were considered off-limits for UAL. This included arms, inner thighs, face and submental area/jaw line, and harvesting of fat for autologous fat transfer. VAL can be successfully use in male gynecomastia with and without tissue resection. The use of ultrasonic surgery devices in the female breast remains controversial, yet UAL, VAL, and Harmonic Scalpel (Ethicon Endo Surgery, Cincinnati, OH, USA) can be effectively used, with appropriate informed consent. VAL appears to work well in combination with excisional body contouring procedures, such as limited abdominoplasty, standard abdominoplasty, lipoabdominoplasty, body lifts, and brachioplasty, in my experience. It is possible to use this technology in a discontinuous fashion for undermining and freeing up of zones of tissue adherence for the purpose of mobilizing tissue.

Hoyas and Millard have developed a high-definition multiplanar VAL approach that enhances surface contour by emphasizing regional muscle group definition. This approach appears successful in the use of superficial VAL, without the serious complications reported in superficial UAL and conventional cannula lipoplasty [22]. This appears to be a technique that should be performed by surgeons that are experienced in the safe use of VASER lipoplasty.

55.19 Discussion

From this discussion, there are a variety of elements regarding technology, physics, and process of lipoplasty that could be improved to change the quality of patient outcomes. These consist of Precision, Finesse, Safety, and Technology. Success in performing contemporary lipoplasty involves the following elements:

- Patient Satisfaction Pays
  - Improve the quality of the experience for the patient
  - Treat anatomic areas to enhance body contours
- Patient Safety Pays
  - Diminish re-op incidence = professional liability concerns
  - Excessive resection = long-term lipoplasty defects that require body lifts or fat grafts to correct
  - What is the role and benefit of general anesthesia for lipoplasty?
- Precision Pays
  - Role of measurements (spreadsheets and data forms), precise technique, observance of clinical end points, and quality improvements
- Technology Pays
  - Avoidance of former UAL/SAL complications

- High efficiency solid probes; vented cannula minimize tissue matrix trauma
- Tools and techniques trump the Surgeon (most lipoplasty complications relate to surgeon-related factors)

While surgical lipoplasty remains a mainstay of body contouring surgery, there are even newer technologies that are being researched to utilize high-intensity focused ultrasonic energy (HIFU) from an external transducer through the skin to disintegrate fat deposits. Pharmacologic approaches to body fat reduction are also being researched in order to obtain data regarding safety and effectiveness. Predicatively, the future may involve a combination of lipoplasty technologies, merged with imaging and computer modeling.

Our personal journey as professional surgeons has shown that there is often more to consider than just technique and that management of the entire cycle of care allows for better quality and safety versus being preoccupied with surgical technique. Take the time to look at how you perform lipoplasty in 2007 and ask yourself if you are really at the state of the art, versus repetitively performing lipoplasty of yesteryear. You future will be bright if you can adopt a mindset of quality improvement, precision, finesse, and safety in lipoplasty. It comes down to your personal examination of the entire process to make it better and safer.

55.20 Research Opportunities

As you can understand from this list, lipoplasty is not a mature technique and there is still the need for more research to work on these unanswered questions. Oddly, despite the great number of lipoplasty procedures that have been performed since inception of this technique, there still exists abundant opportunities for basic and clinical science research in this area. While there is widespread clinical use of this technique and excellent clinical outcomes, little has been done to understand the following:

1. Histological changes of tissue following lipoplasty, including energy-based lipoplasty devices?
2. What is the ultimate cannula design that will be the most specific for fat and least injurious to the collagen tissue matrix?
3. What is the role of garments after lipoplasty and necessary amount of compression?
4. What is the mechanism by which foam dressings diminish ecchymosis after lipoplasty?
5. To what extent can skin retraction be safely produced by lipoplasty techniques?
6. How much lidocaine is really needed in wetting solutions?
7. What is the long-term effect of using ultrasonic lipoplasty (UAL, VASER-assisted lipoplasty) for breast reduction procedures?
8. How to use lipoplasty technique to facilitate noncontiguous soft tissue undermining for incisional body contouring procedures (the "lipoabdominoplasty" and body lifts)?
9. Predictive modeling of amounts of fat aspirate based on imaging of tissue areas?
10. What is the role of the so-called "zones of adherence" and tissue layers in the clinical performance of lipoplasty?
11. How safe is lipoplasty performed in situations of minimal sedation or monitored anesthesia care over general anesthesia?

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S/N 10/600,118 PATENT

CONF. NO. 9143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William W. Cimino	Examiner:	Laura A. Bouchelle
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19US01
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

DECLARATION UNDER 37 C.F.R. § 1.132
BY DR. MARK L. JEWELL, M.D.

EXHIBIT C

ARTICLE:

Jewell, M.L., Fodor, P.B., DeSouza Pinto, E.D., Al Shammari, M. A., Clinical Application of VASER-Assisted Lipoplasty: A Pilot Clinical Study, Aesthetic Surgery Journal, March/July 2002 22:2, p 131-146

Clinical Application of VASER–assisted Lipoplasty: A Pilot Clinical Study

Mark Laurence Jewell, MD; Peter Bela Fodor, MD; Ewaldo Bolivar de Souza Pinto, MD; and Mussab Abdulrahman Al Shammari, MD

Background: *Although lipoplasty is the most frequently performed aesthetic surgical procedure, ultrasound-assisted lipoplasty (UAL) has not been widely adopted because of its increased potential for complications, complex and bulky instrumentation, additional cost, and steep learning curve.*

Objective: *We report on the use of the VASER ultrasound device in lipoplasty procedures and compare the clinical outcomes obtained by means of VASER-assisted lipoplasty with those of other UAL devices.*

Methods: *A superwet technique was used, and the wetting solution was uniformly distributed in the intended treatment area. Skin protection measures included use of specially designed skin ports to protect the incision edges and wet towels adjacent to the port locations. Access incisions were 3 to 4 mm in length. The VASER device was used in VASER (pulsed ultrasound) mode by 2 investigators (P.B.F. and M.L.J.); the continuous ultrasound mode was used by these investigators only if tissue emulsification was not readily achieved by using the VASER mode. A third investigator (E.B.d.S.P.) primarily used the continuous mode. Effective fat fragmentation in either mode was achieved by a maximum of 1 minute of treatment time per 100 mL of infused wetting solution.*

Results: *In a series of 77 patients treated by 3 different clinicians, satisfactory results were obtained with no major complications. This contrasts with an incidence of complications of 7.9% (median, 4.9%) for first- and second-generation UAL devices as determined by statistical analysis of the literature.*

Conclusions: *The initial clinical experience with VASER-assisted lipoplasty indicates that it is a safe and efficient technique for body-contouring surgery.* (Aesthetic Surg J 2002;22:131-146.)

Although lipoplasty is the most frequently performed aesthetic surgical procedure,[1,2] ultrasound-assisted lipoplasty (UAL) has not been widely adopted because of an increased potential for complications,[3,4] complex and bulky instrumentation, additional cost,[5] and steep learning curve.[6]

Historically, a variety of approaches have been used to evacuate fatty deposits during lipoplasty. Initially, improvements in lipoplasty outcomes were linked to advances in aspiration cannula tip design and changes in diameter. Despite these improvements, limitations of the technique included blood loss, postoperative ecchymosis, limited effectiveness in fibrous areas of the body, and surgeon fatigue.

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Wetting Solutions

The next significant advance in lipoplasty was the introduction and use of wetting solutions. Illouz is credited as the first to use wetting solutions during lipoplasty procedures. Currently, the infusion of wetting solutions containing epinephrine and local anesthetics is an integral part of lipoplasty techniques. Lipoplasty performed without the infiltration of wetting solutions ("dry technique") produces significant surgical blood loss (aspirate contains 20% to 45% blood) and postoperative bruising.[7-9] The "wet technique" involves the infiltration of small amounts of saline solutions, regardless of the volume of aspirate, with or without pharmacologic additives. Hetter[10] first reported that the use of solutions that contained dilute epinephrine reduced blood loss to 15% to 30% of the aspirate. Fodor[11] expanded the concept of wetting solutions to the "superwet technique," in which larger amounts of solutions were used during lipoplasty (infiltration-to-aspiration ratio of 1:1). When this technique is used, blood loss in the aspirate, measured as lipocrit, is usually less than 1%.[12] UAL and suction-assisted lipoplasty (SAL) have similar lipocrits.[13,14] Klein advocated even higher volumes of infiltration (infiltration-to-aspiration ratio of 3 to 6:1), to the point that the tissue developed significant turgor; this was generally defined as the "tumescent technique."

The proper use of wetting solutions results in diminished blood loss, reduced postoperative bruising, and enhanced patient comfort. On the other hand, overzealous use of wetting solutions can result in systemic fluid overload, and excessive amounts of local anesthetics intended as regional anesthesia may have deleterious systemic effects.[15-17] Before the introduction of the tumescent technique in the early 1990s, traditional limited SAL was a very safe and effective procedure.[18]

Unfortunately, much confusion regarding wetting solutions in lipoplasty still remains despite multiple previous publications.[19-23] A detailed description is beyond the scope of this article. Nevertheless, a definition of terminology can be found in a recently published editorial.[20]

Energy-based Devices

Another major advance in lipoplasty involved the addition of techniques that used energy-based devices such as UAL, external UAL, and reciprocating cannula lipoplasty, known generally as *power-assisted lipoplasty* (*PAL*). The mechanism of tissue interaction for the PAL devices appears to be similar to that of traditional lipoplasty in that it involves suction-assisted blunt avulsion/aspiration of fat through the ports of a mechanically reciprocating cannula.[23-25] Other technologies, such as the application of laser and microwave energy[26] for fat fragmentation, have been tried experimentally.

The use of continuous ultrasound to produce fat fragmentation in lipoplasty was first popularized by Scuderi et al.[27] First-generation devices (SMEI, Casale Monferrato, Italy) delivered continuous ultrasound through solid, blunt-tipped probes (4 to 6 mm in diameter) to pretreat (fragment) fat before evacuation.[28] Second-generation UAL machines—as popularized by Lysonix, Mentor, and other manufacturers—used 5-mm diameter hollow cannulas that would allow for simultaneous fat fragmentation and aspiration.[29,30] Even by using a cannula with this external diameter, the internal lumen has a diameter of only 2 mm, making the aspiration function generally inefficient. Although there were slight differences in function, both the Lysonix and the Mentor devices were designed to produce continuous ultrasound energy to accomplish fat fragmentation and both incorporated the simultaneous aspiration function. Access incisions for traditional UAL were relatively long (ie, up to 1 cm in length) to accommodate large UAL instrumentation and skin protectors.[28,30] UAL devices that simultaneously infiltrate wetting solutions through an external sheath (sheath systems) do not provide any additional benefits during UAL procedures. In addition, the sheath-style UAL cannulas are reported to have more resistance to passage through tissue.[31]

Ultrasound, when applied internally to fatty tissue by a metallic probe or cannula, is thought to break down cells by means of 3 mechanisms: cavitation, thermal effect, and direct mechanical effect.[32-36] It nevertheless can affect other components of the tissue matrix. The ability of ultrasound to produce skin retraction during UAL is not predictable and is potentially dangerous.[37,38]

The UAL technique was taught through a standardized curriculum at regional instructional symposia sponsored by the UAL Task Force, a coalition of major plastic surgery organizations that represented the American Society for Aesthetic Plastic Surgery, the Aesthetic

Surgery Education and Research Foundation, the American Society of Plastic and Reconstructive Surgeons, the Plastic Surgery Educational Foundation, and the Lipoplasty Society of North America. Approximately 2000 surgeons received training in 41 courses, which included both didactic and bioskills instruction. UAL is a multistep process that involves infiltration of wetting solutions, internal application of ultrasound to fragment fatty tissue, and evacuation of fragmented fatty tissue emulsion by SAL or PAL cannulas.

Despite the voluminous material covered in UAL training courses, there appeared to be a poor understanding of the basic science of ultrasound and its effect on tissue.[39-41] Few studies have addressed ultrasound's effect on tissues and attempted to quantify the amount of ultrasound power necessary for safe clinical outcomes.

Importantly, many surgeons did not understand the relationship between ultrasound power and efficiency of fat fragmentation. As a result, many relied on larger-diameter UAL cannulas to shorten operating-room time, a choice that also increased the amount of energy applied to tissues. Lengthy application times of ultrasound energy was noted in multiple published articles.[28,38,42]

Without a sufficient understanding of power, probe efficiency, and probe design, it was possible to inadvertently apply excessive ultrasound power to fragment fatty tissue, often at the expense of clinical outcomes and increased surgical complications. Until the work published by Cimino,[41] there had not been a qualitative or quantitative study examining the differences among UAL devices and the power that they can deliver to tissues. His article also defined the variables controllable by the surgeon that can ultimately affect clinical outcomes.

Despite initial enthusiasm for UAL, it became apparent to those who used these devices that there were both technical (equipment) limitations and surgical complications attributable primarily to application of excessive amounts of ultrasound energy during lipoplasty. Complications with second-generation ultrasound lipoplasty devices were related to the amount and duration of energy applied to fragment adipose tissue. Most UAL cannulas required high levels of ultrasound energy for fat fragmentation. Excessive application of ultrasound energy can produce internal cavity formation that could lead to seroma or even pseudobursa formation or delayed resolution of swelling, or both.[43] Lateral movement of UAL cannulas or probes could produce thermal damage to deep tissues along the sides of the cannulas. In addition to prolonged tissue induration, painful dysesthesias and sensory changes caused by ultrasound injury have been reported.[42,44] It has been postulated that such adverse effects are a result of the demyelinization of sensory nerve fibers.[45,46] End-hits against the dermal undersurface can produce burns.[37,47] Full-thickness skin loss and hyperpigmentation have also been reported.[48,49] These complications are related to the excessive, inefficient, or improper application and delivery of ultrasound energy.

Outcomes from UAL performed with traditional UAL devices varied from excellent results to significant complications not ordinarily encountered with SAL or PAL.[28,37,38,50] In the meantime, there has been, comparatively speaking, minimal investigation to determine the cause of UAL-related complications. Although hard data do not exist, the clinical use of traditional UAL seems to be declining in the United States, as it has already internationally. As of September 2001, SMEI (first-generation devices) had made a business decision not to actively distribute in the United States, whereas The Lysonix Corporation had ceased selling UAL devices in the United States because of patent-infringement issues.

Beginning in 1995, the senior author (P.B.F.) gained extensive experience with early-generation internal UAL devices. A clinical study was conducted on 100 cases making use of a number of different devices.[51] Although no complications were reported, no appreciable advantage over traditional lipoplasty was found and this author gradually abandoned the use of UAL in his practice.

The VASER Device

From a theoretical perspective, ultrasound energy as used within lipoplasty should be viable for the safe and efficient fragmentation of adipose tissue. The search for an improved ultrasound device that would overcome the limitations in UAL has continued. To this end, a "wish list" was developed to help guide engineering efforts to create a third-generation ultrasound device, which would focus on safety, improved design (efficiency), reduced

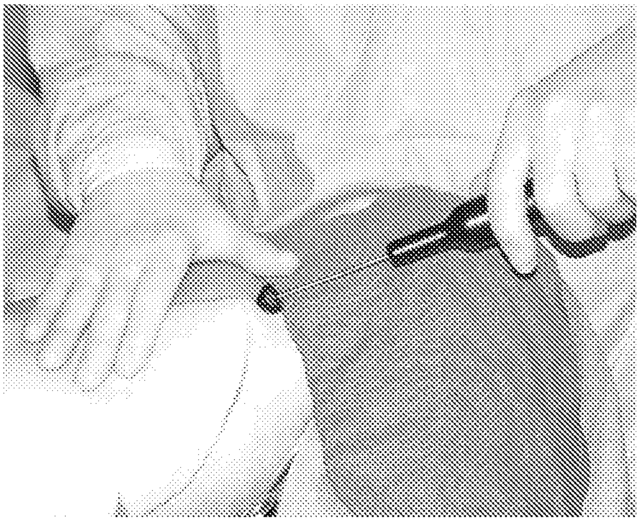

Figure 1. *A 2.9-mm VASER probe and handle with skin protector and wet towel.*

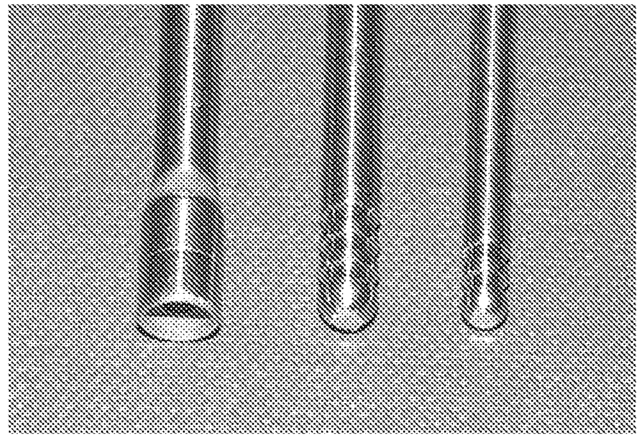

Figure 2. *Comparison of a 5-mm "golf tee" UAL cannula (left), a 3.7-mm 3-groove VASER probe (center), and a 2.9-mm 2-groove VASER probe (right).*

complications, and faster recovery (Fodor PB, oral communication to W.W. Cimino 1998). The clinical objective was to achieve better results and fewer complications attributable to excessive ultrasound exposure.

In response to the "wish list," Sound Surgical Technologies LLC (Lafayette, CO) developed an ultrasound surgical system, the VASER device. This system uses small-diameter solid probes (ie, of 2.9 mm and 3.7 mm) with grooves near the tip to increase fragmentation efficiency. The grooved probe design redistributes the ultrasound energy, transferring some of the vibration energy from the front of the tip to a region just proximal to the tip. Because the efficiency of the fragmentation/emulsification process has been improved by using the grooved design, smaller-diameter probes can be used to achieve rapid and effective fragmentation.

Ultrasound power delivered to the tissues is a strong function of the diameter of the probe.[41] Therefore, smaller-diameter probes deliver less energy to the tissues but still achieve the desired fragmentation and emulsification because of the grooves at the tip and resulting higher efficiencies. For example, the most commonly used clinical settings for the Lysonix 2000 machine (continuous mode) are the 5-mm bullet probe at amplitude settings of 5 to 6, resulting in powers applied to the tissues of 20 to 25 W[41] and efficiencies of 145 to 165 mJ/mm^3. By comparison, the 3.7-mm single-groove solid VASER probe at amplitude settings of 70% to 90% (continuous mode) results in 11 to 13 W applied to the tissues for an efficiency range of 155 to 175 mJ/mm^3. These data show that probe design can result in a nearly 50% reduction in applied power, with improved fragmentation and emulsification capability.

The VASER mode (pulsed ultrasonic energy delivery) reduces the applied power still further while maintaining efficiency. This approach of pulsed delivery of energy is used to achieve the benefits of higher probe vibration amplitudes, but only for short bursts of time. The vibration energy is essentially "off" more than 50% of the time in the VASER mode. For the same 3.7-mm single-groove solid VASER probe, at settings from 80% to 100%, the applied power is 6 to 8 W, with efficiencies from 135 to 155 mJ/mm^3. The VASER mode results in a nearly two-thirds reduction in applied power (compared with that of the Lysonix 2000) with only a slight loss of efficiency. The 2.9-mm diameter probes achieve further reductions in applied power with very high fragmentation efficiencies. Thus, the efficiency of the probe design is critical to the delivery of low levels of applied power. Simply turning down the power on first- and second-generation equipment will not achieve the desired result, because the efficiency of fragmentation falls off so rapidly with decreased amplitude.[41]

In addition, the VASER ultrasound handpiece and its instrumentation are smaller, lighter, less cumbersome, and therefore more "user-friendly" than those of earlier devices. Curved probes have also been developed that

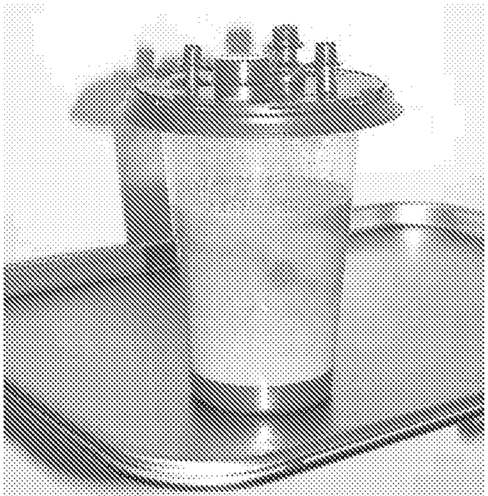

Figure 3. *In all cases, the supernatant fat exceeded 80% of the total volume of aspirate.*

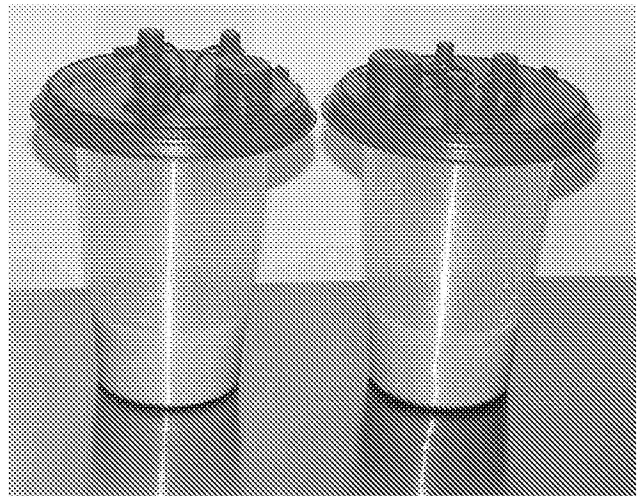

Figure 4. *In some cases, the supernatant fat was 95% of the total volume of aspirate.*

incorporate these technologic advances and are expected to eliminate many of the objections related to probes that cannot be bent or shaped.

Objectives

As with any new form of surgical technology, it is important to examine whether the new approach is superior to the currently existing methodology with respect to the efficiency, safety, and quality of the clinical outcomes. It is also important to compare complications and clinical outcomes with the findings of other reports in the medical literature that involve traditional UAL devices to validate the benefits alleged to be attributable to newer ultrasonic surgical technology. From the perspective of the surgeon, advances in surgical instrumentation also must be superior to the already existing technology with regard to ease of use. In addition, the new device should have an adequate service life. Ideally, if improvements in technology occur, new equipment should contain an upgrade pathway. For that matter, VASER technology is currently being investigated for surgical uses other than lipoplasty. To the best of our knowledge, traditional UAL equipment has not been upgraded, nor have additional surgical applications been developed.

Methods

Three investigators (P.B.F., M.L.J., and E.B.d.S.P.) practicing in different locations and using a standardized approach as much as possible participated in the study. A protocol for the use of the VASER device for VASER-assisted lipoplasty (VAL) was developed. Worksheets were used for data collection. Information was collected concerning the anatomic location of lipoplasty, the amount of wetting solution infiltrated, the amount of supernatant fat, VASER device settings (probe, amplitude, and time), and time required for fat evacuation. During follow-up visits, patient photographs were taken at predetermined postoperative intervals and information was collected regarding ecchymosis, pain, and complications, as well as patient and surgeon satisfaction. Patients with "common lipoplasty indications," including excess fat in the abdomen, hips, lateral thighs, back, and breasts (men only, treated for gynecomastia), were selected for this first study. On the basis of initial results, other anatomic areas were included, such as inner thighs and knees.

Wetting solutions

The superwet technique was used (1:1 volume of infiltrate/volume of aspirate). The wetting solution was uniformly distributed in the intended treatment area and was infused slightly beyond marked lipoplasty boundaries and in all areas of planned port locations. Once a body area was infiltrated, a minimum 10-minute wait elapsed before emulsification was performed with the VASER device. To minimize the risk of potential local anesthetic toxicity or fluid overload, we did not infiltrate all the body areas to be treated at the same time. The amount of lidocaine infused did not exceed 35 mg/kg of body weight in any case.

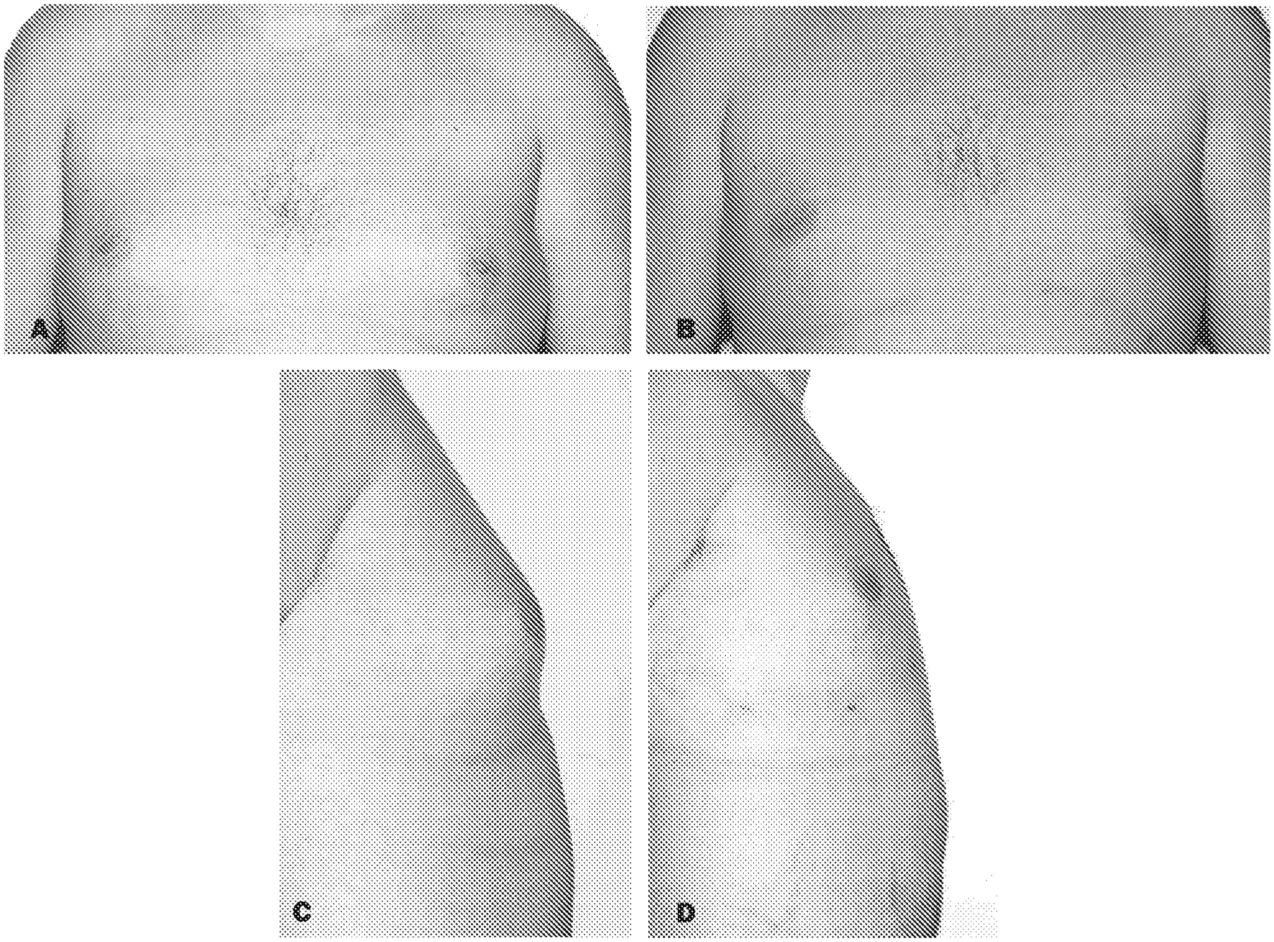

Figure 5. A, C, *Preoperative views of a 20-year-old man with gynecomastia.* **B, D,** *Postoperative views 2 weeks after a VAL procedure that included 500 mL of wetting solution infiltrated per side, application of a 2.9-mm probe for a treatment time of 5 minutes 30 seconds at 90% power, and removal of 350 mL of aspirate per side (90% fat).*

Skin protection

Skin protection was achieved during the delivery of ultrasound energy through the use of specially designed skin ports to protect the incision edges and wet towels adjacent to the port locations (Figure 1). The towel protected the skin from inadvertent contact (external burns) with the shaft of the vibrating probe. The probe movement was performed with a simple axial back-and-forth motion. Levering (applying torque) of the probe was strictly avoided. Levering occurs when the skin port is used as a fulcrum, which focuses the vibration energy at a point of contact with the skin to the extent that a single layer of towel may not provide sufficient skin protection. Access incisions were 3 to 4 mm in length, significantly shorter than necessary with traditional UAL devices.

Tissue type and probe selection

VASER probe selection was determined according to the characteristics of the localized fat deposit to be treated. In general terms, the 3.7-mm probes are intended for rapid debulking of larger volumes of fat. The 2.9-mm probes are intended for smaller volumes and for contouring (Figure 2).

Probe diameter and the number of side grooves on the tip influence how the probe will pass through any given tissue type. For a given diameter, probes with more grooves fragment tissue more efficiently but do not penetrate fibrous tissues as easily because a significant amount of the ultrasonic energy is transferred to the sides of the probe, where the rings are located. Therefore, for a given diameter, probes with fewer grooves are more appropriate for fibrous tissues. Smaller-diameter probes will also

Table 1. Tissue type, probe selection, and amplitude setting

Tissue type	Continuous mode	VASER mode	Amplitude 2.9 mm (3-groove, L or S)	Amplitude 3.7 mm (3-groove)	Amplitude 3.7 mm (2-groove)	Amplitude 3.7 mm (1-groove)
Very soft	Yes	Yes	60-80	70-90	70-90	Not recommended
Soft	Yes	Yes	60-90	80-100	70-90	70-90
Medium	Yes	Yes	70-100	80-100	80-100	70-90
Fibrous	Yes	2.9 mm only	80-100	Not recommended	80-100	80-100
Very fibrous	Yes	No	80-100	Not recommended	Not recommended	80-100

L or S, Long or short probe length (ie, 24 cm/17 cm).

penetrate fibrous tissues more readily than larger-diameter probes, irrespective of the number of rings. For example, if fibrous tissue impeded the passage of a 3.7-mm (3-groove) probe, a 3.7-mm probe with fewer grooves (2 or 1) or a 2.9-mm probe (3-groove) would be selected.

Recommended settings for the VASER device are dictated by tissue type, ultrasound mode, probe selection (diameter and number of side grooves), and amplitude settings. These are summarized in Table 1.

VASER mode versus continuous mode

Throughout this study, the VASER mode (pulsed ultrasound) was found to be sufficiently powerful and, therefore, it was used as the designated method of fat fragmentation by 2 investigators (P.B.F. and M.L.J.). One investigator (E.B.d.S.P.) primarily used continuous ultrasound mode in his series of patients. It was necessary to evaluate the clinical safety, efficacy, and patient outcomes that involve both modes of ultrasound as produced by the VASER device and its solid, grooved probes.

Continuous ultrasound mode was used (P.B.F and M.L.J.) only when tissue emulsification was not readily achieved with the VASER mode, such as in extremely fibrous tissue. Cross-tunneling was used where possible for more uniform fragmentation and to facilitate subsequent aspiration. Each body area was treated once with wetting solutions, fat fragmentation, and aspiration. Repeat fragmentation after aspiration was not performed. Additional aspiration (in part of the nonemulsified fat) was carried out as necessary for optimal aesthetic refinement by means of the SAL or the PAL technique.

Lipoplasty technique

Until an understanding of how efficiently the VASER mode worked was achieved, initial application times were based on an arbitrary minimum of 1 minute of treatment time (continuous or VASER mode) for each 200 mL of wetting solution infused. We found that at times this produced only partial fragmentation of the targeted volume of fat. Subsequently, with experience and depending on the anatomic site, it was determined that effective fat fragmentation could be accomplished by using the guideline of a maximum of 1 minute of treatment time per 100 mL of infused wetting solution with the VASER or the continuous mode.

Loss of resistance to probe movement was used as the primary end point of emulsification, which usually occurred somewhere between the time guidelines described earlier. As one would expect, areas of the body that contained less fibrous fat took less time to reach the desired end point than more fibrous areas. Aspiration was accomplished by using the SAL technique (M.L.J.) or a PAL device (P.B.F. and E.B.d.S.P.). Access incisions were closed with sutures. Topical silicone-backed foam was applied under a compressive garment.

Evaluation of VASER lipoplasty outcomes

Follow-up examinations were conducted at specific intervals on postoperative days 3 to 4 and 7 to 10, as well as 1 to 3 months postoperatively (as much as this was practical). Patient postoperative pain was rated on a scale of 1 to 5, with 1 representing minimal and 5 representing severe pain. Ecchymosis was rated as 1 to 5, with 1 representing no ecchymosis and 5 representing maximal ecchymosis. Patient and surgeon satisfaction were also rated on a scale

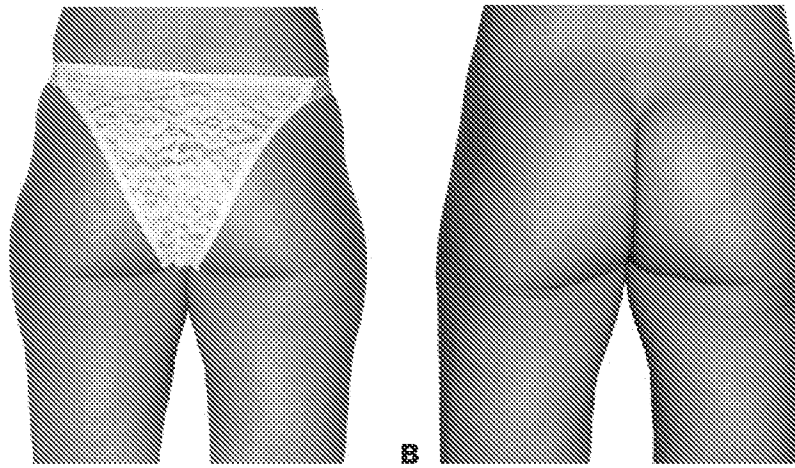
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Figure 6. A, *Preoperative view of a 32-year-old woman.* **B,** *Postoperative view 6 weeks after VAL of the thighs and subgluteal areas with 2200 mL of wetting solution total infiltrate (330 mL for the abdomen, 330 mL for each inner thigh, 300 mL for each trochanteric region, 300 mL for each subgluteal "banana roll"); application of a 2.9-mm probe for a treatment time of 2 minutes 30 seconds per area at 80% power; and removal of 2100 mL of total aspirate (90% fat; 300 mL from abdomen, 300 mL from each inner thigh, 300 mL from each trochanteric region, 300 mL from each subgluteal area [90% fat]).*

Table 2. Clinical outcome of 77 VASER-assisted lipoplasty patients (scale of 1-5)

Category	Outcome rating	Reference scale
Postoperative pain	1-3	1 = no pain; 5 = maximum
Ecchymosis	1-2	1 = none; 5 = maximum
Patient satisfaction	4-5	1 = dissatisfied; 5 = completely satisfied
Surgeon satisfaction	4-5	1 = dissatisfied; 5 = completely satisfied

of 1 to 5, with 5 being completely satisfied. Patients were examined for the presence of other known complications of traditional UAL, SAL, and PAL, such as seroma, infection, burns, dysesthesias, hyperpigmentation, contour irregularities, and prolonged swelling or induration.

Literature search and statistical analysis of traditional UAL complications

To evaluate the safety and efficacy of VASER technology, it was important to compare our clinical experiences, including the incidence of complications in VAL patients, with those in published articles on UAL. We searched the PubMed databases for all clinical articles from indexed journals that appeared in English from 1980 to the present with the keywords *assisted*, *ultrasound*, and *liposuction,* obtaining 73 articles. We also searched any references given in these articles that had the same keywords, as well as the keyword *complication.* In addition, we searched the *Aesthetic Surgery Journal* from January/February 1989 to November/December 2001 for any articles containing these same keywords, including the keyword *complication.* The yield from this last search was 20 additional articles. Therefore, the total number of articles found through our literature search was 93. All these articles were reviewed. Major and life-threatening complications were not included in our analysis. We specifically looked at the following 9 complications: (1) seroma, (2) induration, (3) alteration in sensation (dysesthesia and hyperesthesia), (4) burns (access site), (5) distant burns (end hits), (6) skin necrosis, (7) cellulitis, (8) pigmentary changes, and (9) prolonged swelling.

We found 17 articles in which these complications were reported. We assumed that the complication rate was 0 for any of these individual complications that were not reported in each of the 17 articles (ie, in the articles that reported at least some type of UAL-related complication).

In some of these articles, although reference was made in

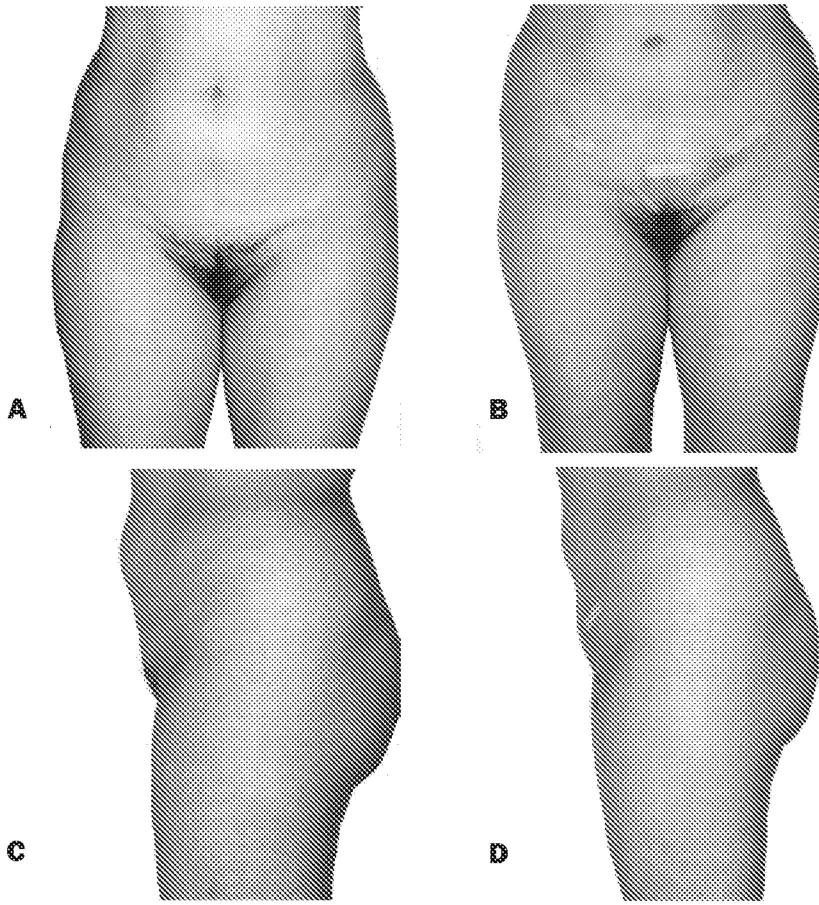

Figure 7. A, C, *Preoperative views of a 52-year-old woman.* **B, D,** *Postoperative views 2 weeks after VAL of the abdomen with 750 mL of wetting solution infiltrate (total), application of a 2.9-mm probe for a treatment time of 4 minutes at 90% power, and removal of 500 mL of total aspirate (90% fat).*

the text to various complications, the authors did not specify the percentage of patients in whom these complications were observed. Similarly, in some articles, induration was mentioned in the body of the article but was not listed as a complication. Complications appear to be reported in these papers on a per-patient basis. In the end, 14 articles appeared to have valid data regarding UAL-related complications that could be subjected to statistical analysis. In one article by Lack,[4] 10 complications were reported in 6 patients. This was classified as a 100% incidence of complications in this specific series for the purposes of statistical analysis.

Three of the 17 articles were not used. A study by Kloehn[30] reported only an overall 3% complication rate without categorizing complications. A study by Commons et al[50] reported 217 seromas, which occurred in 1085 surgical sites in 117 patients. This article was not included in the statistical analysis because of incomplete categorization of reported complications. A chapter by Gingrass[52] was not used because it appeared to be a review article.

Results

Clinical outcomes

Within the context of this pilot study, the emphasis was on the evaluation of a new lipoplasty technology (the VASER device) with regard to its safety, efficacy, and patient outcomes as compared with the reported experiences of other investigators who have used traditional UAL. Data on volumes of wetting solutions and fat aspirate, mode of energy used (pulsed versus continuous), time of application of ultrasound, and evacuation of fat were collected; however, the statistical analysis of these findings was not the primary emphasis of this pilot study and therefore will be mentioned only in general terms. The maximum length of follow-up time with respect to outcome of VAL has been 6 months (as long as practically feasible).

Table 3. Complication rates per report from 14 articles*

Author	No. of UAL patients	Total no. of complications	Overall complication rate (%)
Beckenstein and Grotting[28]	100	15	15
Lee et al[53]	35	0	0.0
Tebbetts[55]	70	0	0.0
Ablaza et al[36]	55	13	23.6
Rohrich et al[42]	114	5	4.4
Gilliland et al[57]	766	13	1.7
Maxwell and Gingrass[58]	250	33	13.2
Fodor and Watson[51]	100	0	0.0
Scheflan and Tazi[37]	800	112	14.0
Agaoglu and Erol[59]	37	2	5.4
Lack[4]	6	10	100†
Tebbetts[56]	70	0	0.0
Kenkel et al[54]	296	7	2.4
Baxter[43]	175	16	9.1
Analysis			
Totals	2874	226	7.9 incidence
Maximum	800	112	100
Minimum	6	0	0.0
Median	100	8.5	4.90
Mean	205.3	16.1	13.5 average

UAL, Ultrasound-assisted lipoplasty.
*All reports were reviewed for the following 9 complications: (1) seroma, (2) induration, (3) alteration in sensation (dysesthesia and hyperesthesia), (4) burns (access site), (5) distant burns (end hits), (6) skin necrosis, (7) cellulitis, (8) pigmentary changes, and (9) prolonged swelling. Other complications, if present, were not included.
†Each of the 6 patients reported multiple complications.

The clinical outcome of each patient was tabulated with regard to the subjectively rated parameters of pain, ecchymoses, patient satisfaction, and surgeon satisfaction.

The maximum amount of fat aspirate did not exceed 4000 mL in any one patient. In all cases, the supernatant fat exceeded 80% of the total volume of aspirate (Figure 3). In some cases, it was as high as 95% (Figure 4). Neither blistering from the silicone-backed foam nor pressure-induced ulcerations from surgical garments were encountered in any patients.

In addition, for the 77 patients who underwent VAL by 3 different clinicians, no complications of the sort that were analyzed in this article with respect to traditional UAL were found. No complications such as seromas, prolonged dysesthesias, burns, induration, contour irregularities, hyperpigmentation, or prolonged swelling were observed in any of 77 patients involved in this study. Recovery was uneventful. There was 0 incidence of revisionary lipoplasty or other secondary body-contouring procedures to improve results obtained in this series.

Clinical outcomes from treatment with VAL are summarized in Table 2 and illustrated in Figures 5 through 11. Pain was average, with ratings in the 1 to 3 range. Bruising and swelling were minimal, with ratings in the 1 to 2 range. Patient satisfaction and surgeon satisfaction were both good, with ratings in the 4 to 5 range for each. One patient who underwent VAL of the thighs and trunk also underwent SAL of the calf and ankle regions. She developed significant ecchymoses in the calf region from the SAL, but did not have any complications from the VAL component of her treatment.

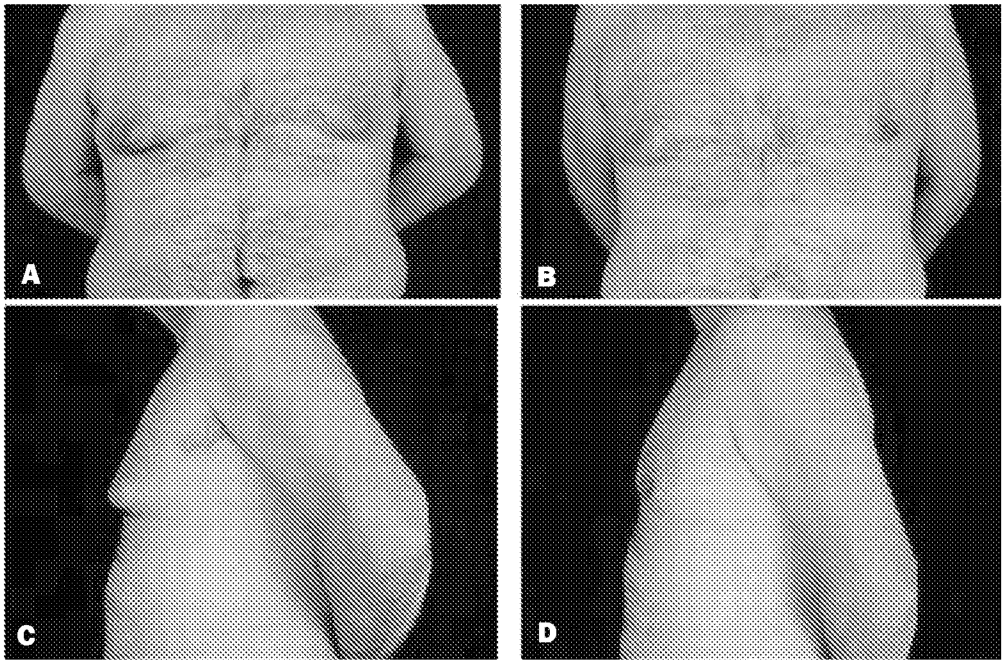

Figure 8. A, C, *Preoperative views of a 33-year-old man with gynecomastia.* **B, D,** *Postoperative views 6 weeks after VAL with 250 mL of wetting solution infiltrated per side, application of a 2.9-mm probe for a treatment time of 1 minute 7 seconds/1 minute 41 seconds at 80% power, and removal of a total of 230 mL of aspirate (85% fat).*

Literature search results

Statistical analysis of complications involving UAL in the 14 selected articles revealed a rate of complications of 7.9% overall (total complications divided by total patients), a 13.5% overall mean rate (average of individual rates), and a median rate of 4.9% when first- or second-generation UAL devices were used (Table 3). By comparison, the complication rate for the 77 patients in this pilot study was 0% in all categories. These essentially complication-free VAL results compare very favorably with reports of complications such as seroma, prolonged dysesthesias, tissue induration, and burns at the access incisions and at distant locations concurrent with the use of traditional UAL devices (Table 4).

Discussion

Within the context of this multicenter pilot study, we have used the VASER device to pretreat fatty deposits in 77 patients seeking improvement in body contour through lipoplasty. Our results indicate that the pretreatment (fragmentation) of fat by using pulsed or continuous ultrasound delivered through grooved, small-diameter solid probes is efficient and safe. Satisfactory to excellent clinical outcomes were observed in all patients enrolled in the study.

In most instances, the aspirate contained approximately 80% or greater supernatant fat. Blood loss appeared minimal, judging from the pale infranatant component of the aspirate. Postoperative edema and ecchymosis, determined through analysis of patient photographs and subjective clinical observations, were also quite minimal. Postoperative pain appeared average for lipoplasty patients. The patient recovery rate appeared similar to that encountered when traditional SAL or PAL is performed, along with use of the superwet technique. Importantly, there were no occurrences of the prolonged discomfort and burning sensations that have been reported for earlier-generation devices.[37,43,44]

We believe that this device represents a technologic advance over earlier generations of UAL equipment. The most important effect of these improvements (probe design and pulsed delivery of energy) is greater fragmentation efficiency and reduction of complications and side effects such as internal burns, seroma formation, skin necrosis, rippling, and painful dysesthesias, which have been reported in conjunction with the use of other UAL devices. We believe that with the use of good clinical judgment and precise surgical technique, surgical complications formerly attributed to continuous-wave UAL devices can be significantly reduced or eliminated with VASER technology.

Table 4. Individual UAL complication rates from 14 articles

Complication type (2874 UAL patients)	No. reported	Maximum incidence per series (%)	Minimum incidence per series (%)	Median incidence per series (%)	Mean (average of individual rates) (%)	Overall total incidence (%)
Seroma	62	21.8	0	1.25	4.8	2.2
Sensation change	66	83.3	0	0.20	7.0	2.3
Induration	3	50	0	0.00	3.6	0.1
Burns at access site	2	1	0	0.00	0.1	0.1
Distant burns	4	3	0	0.00	0.2	0.1
Skin necrosis	43	16.7	0	0.00	1.6	1.5
Cellulitis	2	0.3	0	0.00	0.0	0.1
Hyperpigmentation	35	4	0	0.00	0.5	1.2
Prolonged swelling	8	4.6	0	0.00	0.3	0.3

In addition, we noted that the time necessary for fragmentation and removal of fatty tissues using the VASER equipment is no longer—and in many cases is shorter—than the time required for removal of the same amount of tissue by means of traditional lipoplasty. One of the major objections to the earlier-generation UAL devices/techniques was the length of the procedure compared with that of traditional lipoplasty.[60] The VASER also significantly reduces the surgeon's effort, especially in treating more fibrous tissues. To date, we have not observed any mechanical failures of the VASER equipment or any tip degradation of the VASER probes. According to the manufacturer, a single probe should have a service life of approximately 100 VAL cases, depending to some degree on the complexity of the average case.

Having used the solid-probe technology of VAL, we believe that it is worthwhile to consider abandoning simultaneous fat fragmentation and aspiration through hollow UAL cannula designs. Traditional UAL devices combine inefficient probe designs, which require high levels of power to fragment subcutaneous fat, owing to their very limited aspiration capability because of their small internal lumens.[61] In addition to the targeted adipocytes, other structures such as nerves, collagen fibers, vessels, and lymphatics may be drawn (pulled) to the cannula port, exposing them to damage by ultrasound energy. Moreover, some of the hollow cannula designs ("golf tee") have sharp leading edges that can inflict additional mechanical injury to tissue.[51]

In retrospect, the choice of hollow UAL instrumentation, aiming at simultaneous emulsification and suction as the preferred method, which was advocated initially and taught at the UAL courses, is potentially more hazardous and less efficient than the use of a solid probe for fat fragmentation followed by a separate, and much more efficient, aspiration phase. Traditional UAL cannulas simultaneously remove not only the emulsified tissue but also the fluids that protect adjacent tissues from the ultrasound energy. We disagree with earlier statements that visual feedback of emulsified fat with use of a hollow UAL cannula offers a benefit in terms of determining clinical end points for fat fragmentation.[58,61,62] The "loss of resistance" and time guidelines discussed earlier provide much more intuitive and effective feedback/guidelines. Repeated application of UAL to the undersurface of the dermis after evacuation of the emulsified fat for the purposes of stimulating skin retraction (the so-called fourth step) appears hazardous and unpredictable at best.[37,63]

Conclusion

Historically, we as surgeons have witnessed the expanded application of medical lasers when the concept of pulsed-energy delivery was discovered and applied to these devices (Coherent Ultrapulse Laser). Laser technology has evolved from the development of a continuous-wave, high-power device to the development of a device that efficiently delivers pulsed laser energy capable of a more selective effect within the target tissue (eg, for skin resurfacing, laser hair removal, vascular

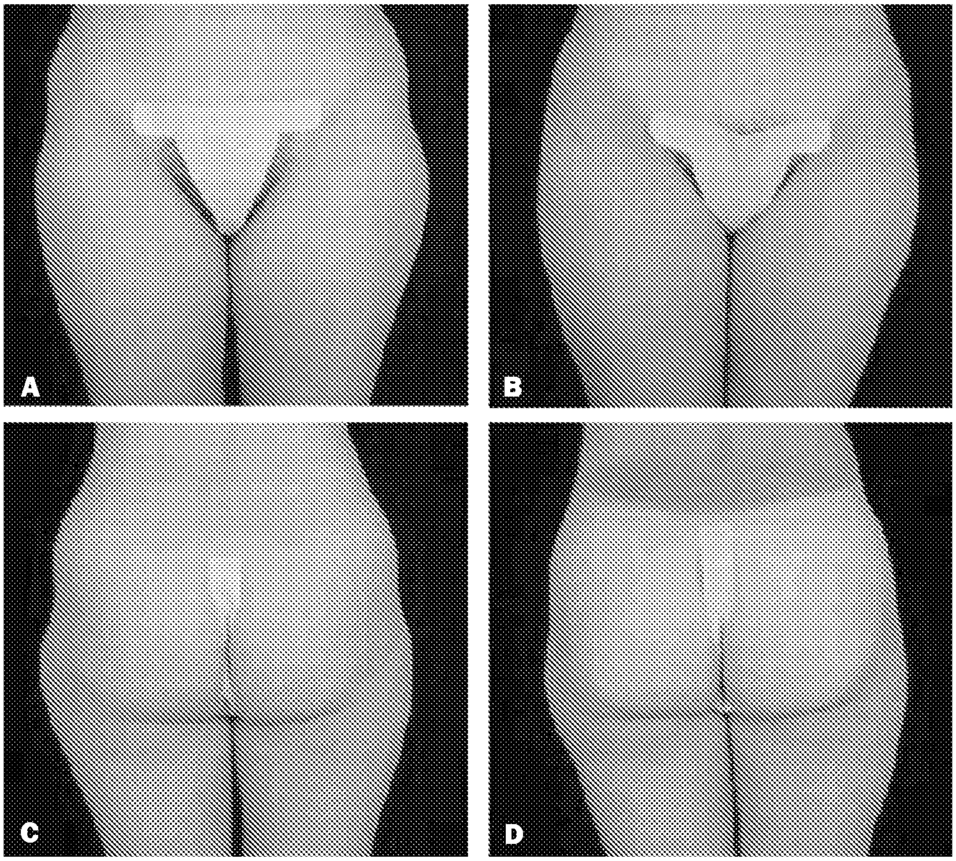

Figure 9. A, C, *Preoperative views of a 29-year-old woman.* **B, D,** *Postoperative views 2 weeks after VAL of the trocanters and hip regions with a total of 1600 mL of infiltrate, application of a 3.7-mm probe for treatment times of 1 minute 26 seconds per side for the trocanters and 1 minute 16 seconds/1 minute 51 seconds for the hips at 80% power, and removal of a total of 1831 mL of aspirate (85% fat).*

laser). A similar paradigm has occurred with the development of the VASER, as compared with that of traditional UAL devices.

We believe that the use of ultrasound for lipoplasty deserves to be revisited because of technologic advances incorporated in the VASER. From the results of this pilot study, it appears that this device, in the hands of a surgeon who is trained in UAL, can produce excellent results with a lower risk of complications than has been reported for earlier UAL equipment. The VASER appears to function in a complementary fashion when used with the SAL and PAL techniques.[25]

The VAL approach brings us closer to all of the theoretical and practical benefits of safe and efficient fat fragmentation without the high complication rates observed and reported with the use of traditional UAL devices. This is the result of improvements in instrumentation and surgical technique, proper use of wetting solutions, and understanding of how to best use ultrasound energy for fat fragmentation. We agree with Courtiss[64] that new technologies must be evaluated by means of scientific methods as opposed to market-driven forces.

UAL education efforts in future training courses should discuss how ultrasound power is delivered to tissue in terms of probe design and efficiency, as well as in terms of the quantitative amount of energy that will be applied. The most important underlying theoretical concept with regard to success is that the surgeon should use the minimum amount of ultrasound power necessary to fragment/precondition fatty tissue for subsequent aspiration and to prevent damage to other elements of the tissue matrix and surrounding tissues. Irrespective of the approach selected for lipoplasty (SAL, UAL, PAL, VAL), complications can potentially occur if these technologies are improperly used.

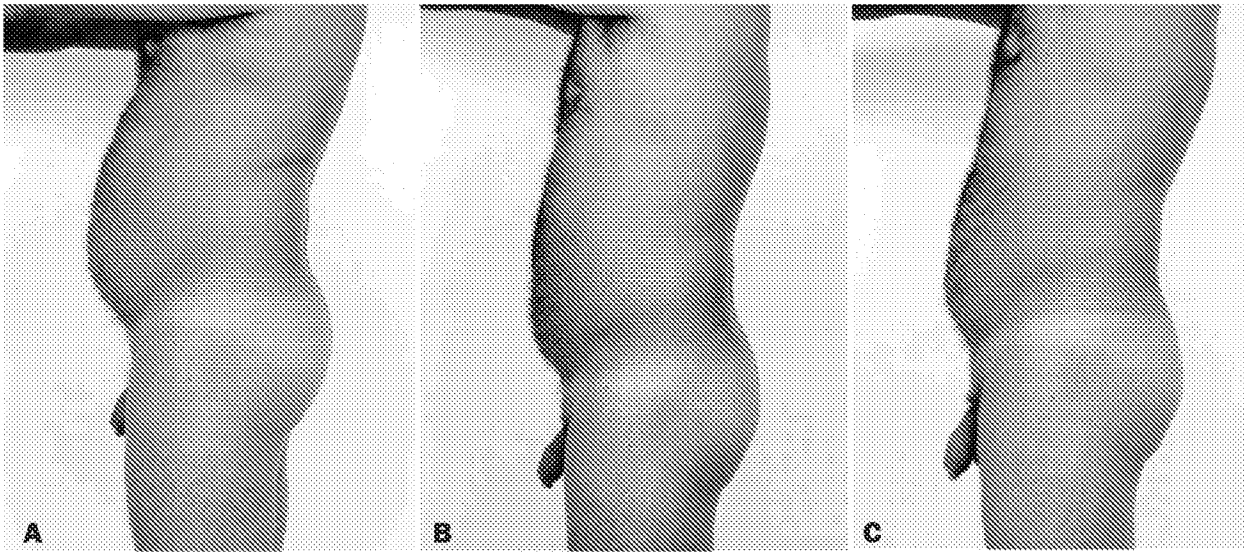

Figure 10. A, *Preoperative view of a 34-year-old man.* **B,** *Postoperative view 3 months after VAL of abdomen with a total of 1700 mL of infiltrate, application of a 3.7-mm probe in continuous mode for a treatment time of 9 minutes 18 seconds at 90% power, and removal of 1100 mL of aspirate (80% fat).* **C,** *Postoperative view 6 months after treatment.*

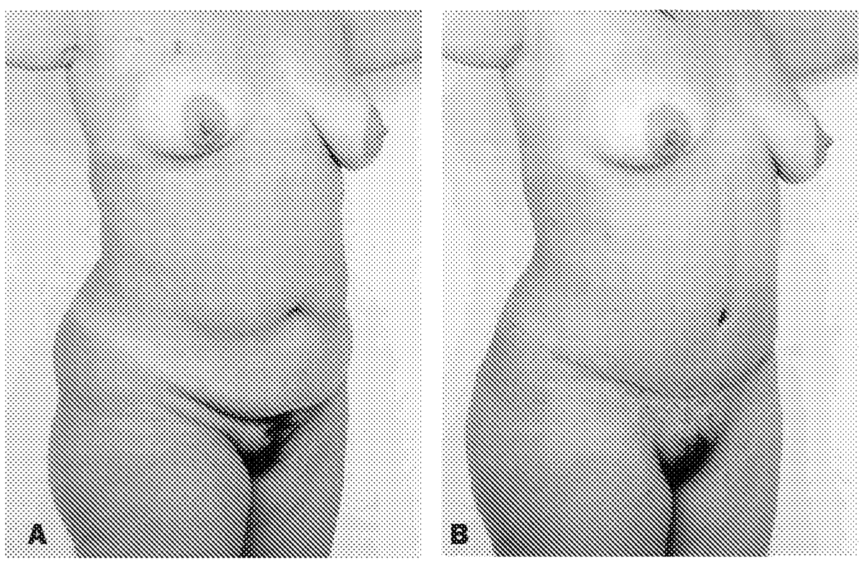

Figure 11. A, *Preoperative view of a 35-year-old woman.* **B,** *Postoperative view 25 days after abdominal lipoplasty/limited abdominoplasty with a total of 2000 mL of infiltrate, application of a 3.7-mm probe in continuous mode for a treatment time of 3 minutes 35 seconds at 90% power, and removal of 1000 mL of aspirate (85% fat).*

In judging by our initial clinical experience with VAL, we believe that VASER technology is a safe and efficient body-contouring modality. On the basis of our evaluation, we believe that the strategy of maximizing probe efficiency to shorten fragmentation time, while reducing probe diameter and ultrasound energy, will minimize collateral tissue damage. In conclusion, we believe that VASER technology, when used correctly, is a powerful lipoplasty tool.

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S/N 10/600,118 PATENT

CONF. NO. 9143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

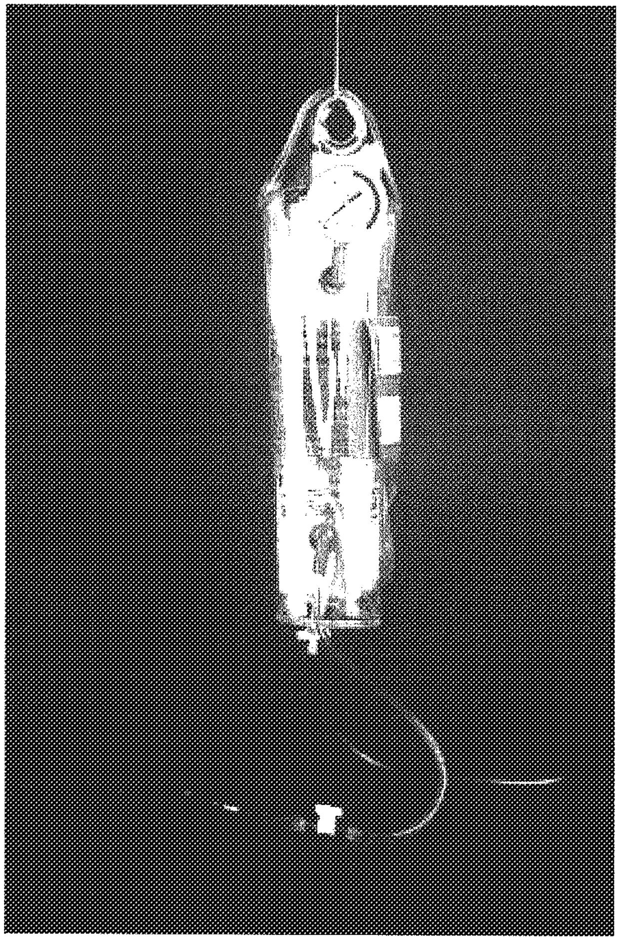
Applicant:	William W. Cimino	Examiner:	Laura A. Bouchelle
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19US01
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

DECLARATION UNDER 37 C.F.R. § 1.132
BY DR. MARK L. JEWELL, M.D.

EXHIBIT D

LITERATURE:

PRODUCT LITERATURE FOR THE BP-CUFF™



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Cat.No.	Description
BP CUFF	BP Cuff 1000ml unit complete
HUN-HAN	Hunstad Infiltration Handle
BP BAG	BP Cuff 1000ml replacement bag
BP CUFF-G	Pressure gauge 0-760 mm Hg
BP CUFF-B	Squeeze bulb, male luer lock & 4-way stopcock
BP CUFF-E	Extension for 3 liter bag
LAM-TUBING	LAMIS™ Tubing Set, Sterile, 10/Box

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